Decision Aid Title

Stenosis of Lower Back: Treatment Options for Spinal Narrowing

Grid Description

Stenosis of the lower back, or spinal stenosis, is a narrowing of the space where the nerves are in your back. It can cause back and leg pain or numbness and tingling in the legs. It might limit what you can do.

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Part 1 - Scoping

Methods

Using an established, structured template that delineates key elements for scoping (i.e., the population, interventions, and key outcomes to consider), we collaboratively agreed with UKSH on the scope of the present evidence report. Scoping was completed on August 29, 2018.

Results – Criteria Selection for Critical Appraisal

Population:

Inclusion criteria

Patients with typical pain from lumbar spinal stenosis

Established diagnosis of spinal stenosis (anatomic correlate for symptoms; e.g., imaging)

All age groups, but primarily >60 years old

Symptoms for >6 weeks

Systematic conservative therapy for >6 weeks (for investigations of nonconservative therapies)

> Post-scoping adjustment: In some evidence reports the use of prior therapy was not explicitly reported in inclusion criteria or patient characteristics. When the inclusion criteria included referral for invasive treatment, assumptions that conservative therapy was attempted before such referral were allowed for evidence that would otherwise meet criteria to be critically appraised

Exclusion criteria

Clear indication for surgery (e.g., cauda equina or symptoms concerning for such; paralysis or loss of control of affected muscle groups such as the bladder), other symptoms that indicate surgery

Intervention and Comparator:

Conservative/noninvasive therapy

Intervention may include different forms of physiotherapy (e.g., exercise, physical therapy, corsets) or medications (e.g., non-steroidal anti-inflammatory drugs), but not epidural injections or surgery. The intention is to report on "Treatment without surgery" rather than a specific treatment.

Comparator may include other active intervention, usual care, waitlist treatment, or untreated control (uncontrolled cohorts). Uncontrolled cohorts are allowed because "Treatment without surgery" is functionally serving as a "control state" for this decision aid so "natural history" or "prognosis" studies will be considered.

Epidural injections

Intervention must include steroids, may include local anesthetics, and does not include other injection therapies. Injections must be applied to lumbar region. Studies including cervical region injections will be excluded.

Comparator must include placebo control (injections with saline or local anesthetics without steroids).

Surgery

Intervention may include decompressive surgery and/or fusion, excluding interspinous device surgeries. Intervention is expected to include conservative modalities, e.g., physical therapy, in addition to surgery.

Comparator may include any conservative/noninvasive therapy.

Outcomes:

FAQ 1: What does the treatment involve?

Include a description of the treatment or procedure. Include frequency of dosing if relevant. Include length of stay if relevant.

Descriptive responses are acceptable, and this does not involve systematic evidence searches, critical appraisal, or evidence synthesis

FAQ 2: Will it help pain or function?

Pain and function are combined into a single FAQ for this evidence review because functional limitation is primarily related to pain. Include resolution of symptoms, improvement in pain, time to pain relief, and improvement in function.

Because one of the options is a hybrid between an active treatment and a control/comparator state, this FAQ will be separated into three subquestions:

FAQ 2a: What is the likelihood of meaningful pain/function improvement with conservative/noninvasive treatment?

We will identify absolute effect estimates from any of three groups: (1) cohorts treated with conservative therapy in control groups of invasive therapy randomized trials (epidural injections or surgery), (2) intervention groups of conservative therapy randomized trials, and (3) prospective cohorts of treatment with conservative therapy.

We will select the most representative outcome(s) available for the specific question phrased in FAQ2a.

FAQ 2b: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with epidural steroid injection?

We will identify relative effect estimates from randomized trials (or systematic reviews of randomized trials) and note the corresponding control event rates. We will select the most representative outcome(s) available for the specific question phrased in FAQ2b. If this is not possible due to the data available, we will summarize the effect estimates available and what these data mean in terms of comparative efficacy.

We will also report the earliest time point where efficacy is noted. Where efficacy is not clearly established, we will report the earliest time point for which pain and/or function outcomes are first reported.

FAQ 2c: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with surgery?

We will identify relative effect estimates from randomized trials (or systematic reviews of randomized trials) and note the corresponding control event rates. We will select the most representative outcome(s) available for the specific question phrased in FAQ2c. If this is not possible due to the data available, we will summarize the effect estimates available and what these data mean in terms of comparative efficacy.

We will also report the earliest time point where efficacy is noted. Where efficacy is not clearly established, we will report the earliest time point for which pain and/or function outcomes are first reported.

FAQ 3: What are the side effects?

Side effects of Interest – in addition to those in the literature – include short-term problems with epidural injections (e.g., hematoma, worsening of pain, headache, flushing in the face, dysphonia/change in voice, CSF leak) and duration of postprocedural pain.

In the absence of adequate sample size to assess for adverse effects in randomized trial evidence, cohort studies will be considered.

FAQ 4: What are the risks?

Risks of interest – in addition to those in the literature – include the general risks of anesthesia, infection and surgical complications.

In the absence of adequate sample size to assess for adverse effects in randomized trial evidence, cohort studies will be considered.

For surgery also consider reoperation rates.

FAQ 5: How long does it take to recover?

Questions of specific interest are time to return to usual activity and time to return to work. Time to return to driving was not of specific interest for the UKSH report but is included due to interest for other stakeholders.

This FAQ is only relevant for the surgery option.

Part 2 - Search and Selection for Critical Appraisal

Methods

First-round searching will consist of searching DynaMed Plus summaries pertinent to the topic. The search starts with DynaMed Plus because DynaMed Plus content is based on a thorough, systematic search and active literature surveillance system.

> Systematic literature surveillance (SLS) has been a cornerstone of creating DynaMed content since its inception. Currently, the SLS team works closely with members of McMaster University's Department of Health Research Methods, Evidence, and Impact to define and refine optimal search strategies, utilizing search terms for methodology and for clinical concepts (especially diagnosis and treatment) for each journal. These filters for PubMed searches are derived from PubMed Clinical Queries, McMaster University Hedges system, and DynaMed search filters and were found to capture >95% of relevant valid articles for use in DynaMed.[1]
>
> [1]Alper BS, Iorio A. Optimising search filters for active literature surveillance: a concordance study. Global Evidence Summit. Cape Town, South Africa; September 2017.
>
> The SLS team, in collaboration with McMaster University, continually evaluates and improves these filters to keep abreast of the ever-changing medical literature landscape. PubMed searches are performed daily. Each article is assessed by an external screener for clinical relevance, then reviewed by internal staff for both clinical relevance and validity. Any disagreements are settled by the Deputy Editor of the SLS team.
>
> In addition, the SLS team continually monitors the Journal source list against the list of journals catalogued in MEDLINE and existing DynaMed content to determine the set of journals that provide the highest yield for valid, clinically relevant content. As of November 2018, 507 Journals are systematically searched (see http://dynamed.com/home/content/content-sources). The journal selection threshold leads to routine adjustments to the number of journals selected.

Second-round searching will involve PubMed/MEDLINE® searches for intervention-specific systematic reviews that are more recent than those identified in first-round searching.

Third-round searching will involve original study tracing from systematic reviews where the systematic review summary was insufficient.

Fourth-round searching will involve searches for original evidence reports. Such searching will be limited to areas considered insufficiently addressed by earlier searches, such as focused concepts published after search dates in systematic reviews.

Additional selective searching, such as tracing citations from articles found or seeking related articles, may be done for additional concepts discovered.

Results

First-round searching – DynaMed Plus:

DynaMed Plus subsection	Number of article citations	Number of studies critically appraised	Relevant for FAQ(s)
Lumbar spinal stenosis topic, Treatment section, Activity subsection ➢ Physical therapy or exercise subsection (Dec 28, 2018)	11	3 (Ammendolia 2013, Delitto 2015, Kreiner 2013)	FAQ2a, FAQ3, FAQ4
Lumbar spinal stenosis topic, Treatment section, Surgery and procedures subsection ➢ Minimally invasive lumbar decompression (MILD procedure) subsection (Dec 28, 2018)	2	1 (Benyamin 2016, a subsequent report of Staats 2016)	FAQ2c
Lumbar spinal stenosis topic, Treatment section, Surgery and procedures subsection, Decompressive surgery subsection (Dec 28, 2018) ➢ Indications and efficacy subsection	16	5 (Delitto 2015, Kreiner 2013, Weinstein 2007, Weinstein 2008, Zaina 2016)	FAQ2c
Epidural steroid injection topic, Efficacy section (Dec 28, 2018) ➢ Spinal stenosis with or without neurogenic claudication subsection	5	2 (Ammendolia 2013, Chou 2015)	FAQ2b

Second-round searching – searches for intervention-specific systematic reviews:

Database	Search string*	Number of search results	Number of studies critically appraised	Relevant for FAQ(s)
PubMed December 26, 2018	Systematic[SB] AND <Lumbar spinal stenosis> AND <Surgery> AND <Pain or function> AND ("2015/01/01"[PDAT] : "3000/12/31"[PDAT])	36	2 (Mo 2018, Zaina 2016)	FAQ2a, FAQ2c
PubMed December 26, 2018	Systematic[SB] AND <Lumbar spinal stenosis> AND <Surgery> AND ((side effects) OR (adverse effects) OR complications) AND ("2015/01/01"[PDAT] : "3000/12/31"[PDAT])	26	2 (Guha 2015, Zaina 2016)	FAQ3, FAQ4
PubMed December 26, 2018	Systematic[SB] AND <Lumbar spinal stenosis> AND <Epidural steroid injections> AND <Pain or function> AND ("2014/01/01"[PDAT] : "3000/12/31"[PDAT])	9	2 (Liu 2015, Manchikanti 2015a)	FAQ2a, FAQ2b
PubMed December 28, 2018	Systematic[SB] AND <Lumbar spinal stenosis> AND <Epidural steroid injections> AND ((side effects) OR (adverse effects) OR complications) AND ("2014/01/01"[PDAT] : "3000/12/31"[PDAT])	6	0	FAQ3, FAQ4
PubMed December 29, 2018	Systematic[SB] AND <Lumbar spinal stenosis> AND <Surgery> AND (return to work)	4	0	FAQ5
PubMed December 29, 2018	Systematic[SB] AND spinal AND <Surgery> AND driving	1	1 (Alhammoud 2017)	FAQ5

*Any phrase enclosed within "<>" is a placeholder for the MeSH explosion that occurs for search terms. Below, the full MeSH corresponding to any such phrase appears in full.

<Epidural steroid injections> = (("epidural space"[MeSH Terms] OR ("epidural"[All Fields] AND "space"[All Fields]) OR "epidural space"[All Fields] OR "epidural"[All Fields]) OR spinal[All Fields]) AND

(("adrenal cortex hormones"[MeSH Terms] OR ("adrenal"[All Fields] AND "cortex"[All Fields] AND "hormones"[All Fields]) OR "adrenal cortex hormones"[All Fields] OR "corticosteroid"[All Fields]) OR ("steroids"[MeSH Terms] OR "steroids"[All Fields] OR "steroid"[All Fields]) OR ("dexamethasone"[MeSH Terms] OR "dexamethasone"[All Fields]) OR ("betamethasone"[MeSH Terms] OR "betamethasone"[All Fields]) OR ("prednisone"[MeSH Terms] OR "prednisone"[All Fields]) OR ("prednisolone"[MeSH Terms] OR "prednisolone"[All Fields]) OR ("methylprednisolone"[MeSH Terms] OR "methylprednisolone"[All Fields]) OR ("triamcinolone"[MeSH Terms] OR "triamcinolone"[All Fields])) AND ("injections"[MeSH Terms] OR "injections"[All Fields] OR "injection"[All Fields])

<Lumbar spinal stenosis> = (("lumbosacral region"[MeSH Terms] OR ("lumbosacral"[All Fields] AND "region"[All Fields]) OR "lumbosacral region"[All Fields] OR "lumbar"[All Fields]) OR lumbosacral[All Fields]) AND ("spinal stenosis"[MeSH Terms] OR ("spinal"[All Fields] AND "stenosis"[All Fields]) OR "spinal stenosis"[All Fields])

<Pain or function> = (("pain"[MeSH Terms] OR "pain"[All Fields]) OR disability[All Fields] OR ("physiology"[Subheading] OR "physiology"[All Fields] OR "function"[All Fields] OR "physiology"[MeSH Terms] OR "function"[All Fields]))

<Surgery> = (("surgery"[Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgery"[All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields]) OR ("surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgical"[All Fields]))

Third-round searching – **original study tracing from systematic reviews:**

Database	Search string	Number of search results	Number of studies critically appraised	Relevant for FAQ(s)
Chou 2015 systematic review	Tracing included randomized trials for detailed critical appraisal, limited to good quality trials	8	1 (Friedly 2014)	FAQ2b
Manchikanti 2015a systematic review	Tracing included randomized trials for detailed critical appraisal, limited to high quality trials	8	2 (Manchikanti 2012, Manchikanti 2015b)	FAQ2b
Zaina 2016 systematic review	Tracing included randomized trials for detailed critical appraisal, excluding trials of interspinous device	5	4 (Amundsen 2000, Brown 2012, Malmivaara 2007, Weinstein 2008)	FAQ2c

Fourth-round searching – searches for original evidence reports:

Database	Search string*	Number of search results	Number of studies critically appraised	Relevant for FAQ(s)
PubMed December 26, 2018	<Lumbar spinal stenosis> AND <Surgery> AND <Pain or function> AND (Randomized Controlled Trial[ptyp] AND ("2017/01/01"[PDAT] : "3000/12/31"[PDAT]))	17	0	FAQ2a, FAQ2c
PubMed December 26, 2018	<Lumbar spinal stenosis> AND <Epidural steroid injections> AND <Pain or function> AND (Randomized Controlled Trial[ptyp] AND ("2014/01/01"[PDAT] : "3000/12/31"[PDAT]))	11	3 (Friedly 2014, Friedly 2017 [additional details for Friedly 2014], Manchikanti 2015b)	FAQ2b
PubMed December 29, 2018	(lumbar or caudal) AND (epidural steroid injection) AND (adverse effects) AND (cohort)	74	7 (Botwin 2000, Botwin 2001, El Abd 2015, Karaman 2011, Kim 2010, Kranz 2015, Plastaras 2015)	FAQ3, FAQ4
PubMed December 29, 2018	epidural steroid injection AND dysphonia	3	1 (Bhat 2005)	FAQ3
PubMed December 29, 2018	<Lumbar spinal stenosis> AND <Surgery> AND (return to work)	40	4 (Herno 1996, Truszczynska 2013, Tye 2017a, Tye 2017b)	FAQ5

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<Epidural steroid injections> = (("epidural space"[MeSH Terms] OR ("epidural"[All Fields] AND "space"[All Fields]) OR "epidural space"[All Fields] OR "epidural"[All Fields]) OR spinal[All Fields]) AND (("adrenal cortex hormones"[MeSH Terms] OR ("adrenal"[All Fields] AND "cortex"[All Fields] AND "hormones"[All Fields]) OR "adrenal cortex hormones"[All Fields] OR "corticosteroid"[All Fields]) OR ("steroids"[MeSH Terms] OR "steroids"[All Fields] OR "steroid"[All Fields]) OR ("dexamethasone"[MeSH Terms] OR "dexamethasone"[All Fields]) OR ("betamethasone"[MeSH Terms] OR "betamethasone"[All

Fields]) OR ("prednisone"[MeSH Terms] OR "prednisone"[All Fields]) OR ("prednisolone"[MeSH Terms] OR "prednisolone"[All Fields]) OR ("methylprednisolone"[MeSH Terms] OR "methylprednisolone"[All Fields]) OR ("triamcinolone"[MeSH Terms] OR "triamcinolone"[All Fields])) AND ("injections"[MeSH Terms] OR "injections"[All Fields] OR "injection"[All Fields])

<Lumbar spinal stenosis> = (("lumbosacral region"[MeSH Terms] OR ("lumbosacral"[All Fields] AND "region"[All Fields]) OR "lumbosacral region"[All Fields] OR "lumbar"[All Fields]) OR lumbosacral[All Fields]) AND ("spinal stenosis"[MeSH Terms] OR ("spinal"[All Fields] AND "stenosis"[All Fields]) OR "spinal stenosis"[All Fields])

<Pain or function> = (("pain"[MeSH Terms] OR "pain"[All Fields]) OR disability[All Fields] OR ("physiology"[Subheading] OR "physiology"[All Fields] OR "function"[All Fields] OR "physiology"[MeSH Terms] OR "function"[All Fields]))

<Surgery> = (("surgery"[Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgery"[All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields]) OR ("surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "surgical"[All Fields]))

Part 3 - Critical Appraisal of Evidence Reports

Methods

For each study selected for critical appraisal, we assessed for criteria needed for Level 1 [likely reliable] evidence ratings in DynaMed's Levels of Evidence criteria in which evidence quality is labeled in 1 of 3 levels:

- **(level 1 [likely reliable] evidence)** for studies with clinical outcomes and minimal risk of bias;
- **(level 2 [mid-level] evidence)** for studies with clinical outcomes and significant methodological or statistical limitations; and
- **(level 3 [lacking direct] evidence)** for reports that do not include scientific analysis of clinical outcomes or for study types that do not include comparisons between groups.

The specific concepts we critically assessed are fully mapped to cover all the criteria used in GRADE. We summarized key concerns identified that reduce the certainty of evidence in categories used for GRADE methods (ie, risks of bias, indirectness, imprecision, inconsistency, and other considerations if relevant). In the study-level summaries inconsistency assessment was applied to consistency of within-study results – this applies to consistency across related outcomes for both original studies and for systematic reviews, and also applies to consistency across studies when applied to systematic reviews.

Results

Characteristics and Results of Critically Appraised Studies/Sources

ALHAMMOUD 2017

Alhammoud A, Alkhalili K, Hannallah J, Ibeche B, Bajammal S, Baco AM. Driving safety after spinal surgery: a systematic review. Asian Spine J. 2017 Apr;11(2):319-327. PubMed Full Text
Relevant to FAQ5

- **Study design:** systematic review
- **Population:** 304 patients from 6 studies (5 lumbar, 1 cervical)
- **Intervention:** selective nerve root block, anterior cervical discectomy and fusion, and lumbar fusion and/or decompression
- **Comparison:** Varied by study, but generally included "age- and sex-matched normal subjects", "age-matched healthy subjects", or "healthy subjects"
- **Outcome:** pre- vs. postoperative driving reaction time
- **Duration of follow-up:** time of discharge to 3 months
- **Certainty: Very low**
    - **Risk of bias:** Controls varied by study.
    - **Precision:** Small sample sizes.
    - **Directness:** Simulator-based reaction time may not accurately reflect real-world driving conditions. Most studies assessed reaction time at infrequent intervals and did not include information on patients' physical and cognitive function, medication use, or pain duration. Specifics of spinal conditions leading to surgery were not provided or analyzed separately.
    - **Consistency:** No meta-analysis or pooling of data performed due to inconsistency.
    - **Other considerations:** Existing literature on driving after spinal surgery is largely based on braking reaction time, assessed using a driving simulator. The act of braking in response to a perturbation is more complicated than this outcome alone, and safe driving is more complicated than braking response alone. Pain medication use and cognitive function should also be considered when making return-to-driving recommendations.
- **Results:**
    - driving reaction time in studies varied based on type of surgery and spinal level of surgery
    - some lumbar surgery studies suggest that driving reaction time may be prolonged by pain and therefore may be improved by analgesic medication; other studies found no correlation between pain and reaction time
    - study results on driving after spinal surgery varied from safe to drive immediately after hospital discharge to abstinence until 3 months after surgery
    - recommendations:
        - for patients undergoing single-level lumbar spinal fusion, resumption of driving as early as 2 weeks is acceptable
        - for patients who undergo multilevel lumbar spinal fusion, it is safe to resume driving 3 months after the surgery
        - individual patients should be evaluated based on age, type of pain medication and frequency of use, history of opioid consumption, and other factors that might affect driving ability

AMMENDOLIA 2013

Ammendolia C, Stuber KJ, Rok E, et al. Nonoperative treatment for lumbar spinal stenosis with neurogenic claudication. Cochrane Database Syst Rev. 2013 Aug 30;(8):CD010712. PubMed
Relevant to FAQ2a, FAQ2b, FAQ3, FAQ4

- **Study design:** systematic review and meta-analysis
- **Population:** 1,851 patients with lumbar spinal stenosis and neurogenic claudication in 21 trials
    - Mean age was older than 50 years in all but 2 trials, in which the mean age was just less than 50 years
- **Intervention:** nonoperative treatments included calcitonin, epidural injections, oral medications, physical therapy, and multimodal nonoperative care
- **Comparisons:** no treatment, placebo, other conservative treatment, or surgery
- **Outcomes:** walking ability, pain intensity, function, quality of life, global improvement
- **Duration of follow-up:** 2 weeks to 10 years
- **Certainty: Very low**
    - **Risk of bias:** All trials appear to have substantial risk of bias though the review text was inconsistent. Results text reported that 4 trials were considered to have an overall low risk of bias, based on their reportedly having met pre-specified criteria that included low risks of bias for both random sequence generation and allocation concealment. However, all 4 of these trials were judged to have "High risk" of bias for both randomization-related risk of bias domains so they did not meet the authors' own criteria for having an overall low risk of bias. No support for the review authors' judgments on the risk of bias domains was provided (i.e., the Cochrane risk of bias tables only reported "Authors' judgment" and did not provide any information under "Support for judgement").
    - **Precision:** No serious concerns.
    - **Directness:** Treadmill Walking Test used in one-third of trials may underestimate walking ability, and patients often are reluctant to walk on a treadmill for fear of falling.
    - **Consistency:** Inconsistency in interventions, controls and outcomes precluded pooled analyses.
- **Results:**
    - Inconsistency in interventions, controls and results precluded using pooled results as reliable results. Key findings reported descriptively by trial. **Adverse effects are bolded.**
    - Physical therapy/exercise:
        - Four trials reporting on exercise/physical therapy modalities were Goren 2010 (N = 45), Koc 2009 (N = 29), Pua 2007 (N = 68), and Whitman 2006 (N = 58).
        - Goren 2010 was three-week trial with three arms: (1) a multimodal intervention including active ultrasound; (2) the same multimodal intervention with the ultrasound turned to off but still applied; and (3) a no exercise, no treatment group. The multimodal intervention included "stretching and strengthening exercises for lumbar, abdominal, leg muscles as well as low-intensity cycling exercises". Active ultrasound was 1 mHz, 1.5W/cm2 intensity in continuous mode, applied to the back muscle for 10 minutes. Follow-up was limited to the three-week period of the trial. This trial provides low-quality evidence that exercise may be better than no treatment for short-term leg pain and function.

- Koc 2009 was a trial with three arms: (1) an inpatient physical therapy program five days a week for two weeks that included applications of ultrasound at 1.5 W/cm2 for 10 minutes, a hot pack for 20 minutes, and transcutaneous electrical nerve stimulation for 20 minutes to the lumbar region; (2) lumbar epidural steroid injections; (3) control group. All groups received oral diclofenac at the same dose and frequency for two weeks. All patients were also trained to pursue a home-based "therapeutic exercise program" that was to be completed twice a day for six months. Follow-up occurred at two weeks and then at months one, three, and six. This trial provides very low-quality evidence that inpatient physical therapy in addition to a home exercise program and oral diclofenac may improve short-term pain intensity, function, and quality of life compared to a home exercise program and oral diclofenac alone. **One patient developed angina pectoris.**
- Pua 2007 was a six-week trial with two arms comparing different exercise modalities. Twice a week for six weeks, the groups engaged in an exercise session lasting a maximum of 30 minutes, with the groups being: (1) an unweighted treadmill regimen where patients were initially instructed to walk with "a relatively pain-free gait" in the first two weeks, and then were "encouraged to exercise at a moderate intensity" in weeks three to six; and (2) an upright bicycle regimen where patients were initially instructed to cycle at a "comfortable pace [of] 50 to 60 rpm" for the first two weeks, and then were "encouraged to exercise at a moderate intensity" in weeks three to six. Those in the cycling group were also instructed to assume a flexed posture in all weeks. This trial provides low-quality evidence of no clear short-term difference between the two exercise regimens tested for any outcome assessed. **One patient reported an increase in symptoms with exercise.**
- Whitman 2006 had two arms with randomized interventions lasting six weeks, but with follow-up occurring at six weeks, one year, and then via a mail survey with an average follow-up time of 29 months. For 45-60 minutes twice a week for six weeks: (1) the "flexion exercise and walking group" engaged in lumbar flexion exercises; subtherapeutic ultrasound; and a progressive level, self-paced treadmill walking program that could extend up to 45 minutes but could be shorter based on the patient's tolerance, and (2) the "manual therapy, exercise, and walking group" engaged in specific exercises – performed both in the clinic and as part of a home program – based on the underlying patient-specific impairments in mobility, strength, and/or coordination; manual physical therapy (thrust and non-thrust) to the thoracic and lumbar spine, pelvis, and lower extremities; and a treadmill program that used a cable and trunk harness to offload a certain amount of the patient's bodyweight while s/he walked as comfortably as possible. This trial provides very low-quality evidence that the "manual therapy, exercise and walking group" intervention may lead to a short-term global improvement compared to the "flexion exercise and walking group" intervention.

- Oral medications:
  - Three trials reporting on oral medications were Matsudaira 2009 (N = 79), Waikakul 2000 (N = 152), and Yaski 2007 (N= 55), each studying a different medication.

        - Matsudaira 2009 was a two-armed, eight-week trial studying the effects of a prostaglandin E1 derivative (n = 39) versus etodolac (an NSAID, which inhibits prostaglandins; n = 40) among patients at four study sites in Japan, offering low-quality evidence that the prostaglandin E1 derivative may improve walking distance and leg pain in the short-term. In both groups, **about 5% of patients reported gastrointestinal upset.**
        - Waikakul 2000 was a two-armed trial with follow-up occurring every month for two years, but with the key difference in intervention (additional vitamin B12, specifically methylcobalamin) only occurring in a randomized fashion for six months. This trial essentially studied the effects of two "conservative treatment" regimens, with one regimen having a higher dose of vitamin B12 (specifically, methylcobalamin). The conservative treatment regimen consisted of education, activity modification, exercise, physical therapy; thrice daily administration of vitamins B1, B6, and B12; and NSAIDs, muscle relaxants, and other analgesics as needed. Both groups received this regimen, but one group (n = 70) received additional vitamin B12 whereas the other group (n = 82) received only the dose that was a standard part of the conservative treatment regimen. This trial offers very low-quality evidence that the aforementioned conservative treatment regimen with additional vitamin B12 may improve walking distance in the intermediate and long-term follow-up periods compared to just the conservative treatment regimen. **There were no reported adverse effects for the group receiving supplemental vitamin B12.**
        - Yaski 2007 was a four-month trial with follow-up periods at 15 days and then at months one through four that studied the effects of gabapentin (n = 28) versus placebo (n = 27) against background therapy in both groups consisting of physical therapy exercises, NSAIDs, and a lumbosacral corset with steel bracing. This trial offers very low-quality evidence that gabapentin may improve walking distance and pain intensity compared to placebo over the intermediate term . **This trial qualitatively reported that some participants randomized to the gabapentin group reported mild to moderate drowsiness and/or dizziness.**
- Parenteral calcitonin:
    - Trial evidence suggests calcitonin offers no benefit – regardless of the outcome assessed or method of calcitonin administration – compared to placebo (Eskola 1992; Podichetty 2004; Porter 1983; Porter 1988; Tafazal 2007; N = 186) or acetaminophen (Sahin 2009; N = 45; Sahin 2009 also specified background therapy for all patients consisting of a physical therapy and exercise program five times a week for 15 sessions). All trials administered calcitonin over the short-term and are considered to offer very low-quality evidence. Porter 1983 (N = 10) had the longest trial duration of 10 weeks. The other trials administered calcitonin over four weeks (Eskola 1992; Tafazal 2007; N = 79), six weeks (Podichetty 2004; N = 55), or eight weeks (Porter 1988; Sahin 2009; N = 87), though Podichetty 2004 had a six-week open-label extension where all participants received calcitonin and Eskola 1992 (N = 39) had follow-up periods extending to 12 months even though the trial therapies were only administered for four weeks. Eskola 1992 and Porter 1983 and 1988 (N = 91) gave calcitonin as an injection; the other trials (N = 140) gave calcitonin intranasally.
- Epidural injections:

- Epidural injections were evaluated in 4 trials. Three out of the 4 had high or unclear risks of bias for all key risk of bias domains, and the fourth did not include a placebo injection control (which is an inclusion criterion for this intervention for our evidence report). All 4 were also included in a subsequent systematic review that compared epidural corticosteroid injections with placebo interventions in patients with spinal stenosis (Chou 2015).

AMUNDSEN 2000
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleâs F. Lumbar spinal stenosis: conservative or surgical management?: A prospective 10-year study. Spine (Phila Pa 1976). 2000 Jun 1;25(11):1424-35; discussion 1435-6. PubMed
Relevant to FAQ2c

- **Study design:** randomized, controlled trial
- **Population:** 31 patients randomized (13 to surgical treatment, 18 to conservative treatment); numerically more men in surgical treatment group than women (9 vs. 4) and more women in conservative treatment group than men (11 vs. 7), but these differences were not statistically significant
- **Intervention:** The surgical procedure was standardized for the purpose of nerve decompression by partial or total laminectomy, medial facetectomy, discectomy, and/or removal of osteophytes from the vertebral margins or facet joints. Hypertrophic ligamenta flava were removed if necessary. No fusions were performed. Selection of the operative level(s) was made by considering primarily the clinically defined level(s), not the severity of the radiologic findings, with one to four levels being operated on either unilaterally or bilaterally depending on the case. Patients were mobilized within 1-2 days and fitted with a brace/orthosis. After 1 week, the patients were transferred to the rehabilitation department for a period of 1 month. Sitting was not allowed during this period, and no specific physiotherapy was given except for instruction and "back school." The patients were encouraged to walk around and move as normally as possible.
- **Comparison:** Patients were fitted with the same orthosis/brace as was assigned to the surgical group and were also transferred to the rehabilitation department for 1 month, but again, "[n]o regular physiotherapy was given, except for instruction and 'back school'". The brace/orthosis was to be worn during the day for all activities, and they were encouraged to walk and move around as normally as possible (as with the surgical group).
- **Outcomes:** Outcomes included visual analogue pain scale, verbal rating scale, subjective change (better, worse, or unchanged), work status, and subjective physician rating (excellent, fair, unchanged, worse), which were reported at different intervals based on the outcome under consideration at 3 months, 6 months, 12 months, 4 years, and 10 years. No outcomes were clearly prespecified or specified as the primary outcome.
- **Duration of follow-up:** 10 years
- **Certainty: Low**
  - **Risk of bias:** Allocation concealment is unclear. No blinding. 10/18 (56%) patients in the conservative treatment group crossed over to surgery. These patients were given the new label of group "RC+", with the patients who were randomized to and stayed in the conservative treatment group being given a label of "RC" (this also led to labeling those randomized to the surgery group as "RS").
  - **Precision:** Very small sample sizes, confidence intervals calculated (below) are wide.
  - **Directness:** No serious concerns

- **Consistency:** No serious concerns
- **Other considerations**: There was 1 death in the group randomized to surgery and one death in the group randomized to control by the 4-year follow-up point and 1 additional death in the group randomized to surgery by the 10-year follow-up point (all 3 deaths of these deaths were from natural causes). Because of crossover and patient deaths, the number of patients in the RS and RC group at 10 years were reported to be 11 and 8, respectively (with 9 in group RC+).

- **Results:**
  - Most outcomes are reported as descriptive statistics. We evaluated in depth the outcome of "no or light pain", which Zaina 2016 also reported in their Cochrane review. Data extracted could vary depending on how crossovers and losses to follow-up were counted. Among the 13 patients randomized to the RS group and the 18 patients randomized to the RC group (with deaths as noted in "Other considerations" above), the following number of patients reported "no or light pain" at the following time points:

Time point	***Randomized to surgery (RS)***	***Randomized to conservative therapy***	***Randomized to and stayed in conservative therapy group (RC)***	***Randomized to conservative therapy group but crossed over to surgery group (RC+)***
3 months	2	7	2	5
4 years	5	2	1	1
10 years	5	4	2	2

    - Comparing surgery vs. conservative therapy via ITT analysis:
      - 3 months: 15.4% (2/13) vs. 38.9% (7/18)
        - RR 0.40; 95% CI, 0.10 to 1.60
      - 4 years: 41.7% (5/12) vs. 11.8% (2/17)
        - RR 3.54; 95% CI, 0.82 to 15.31
      - 10 years: 45.5% (5/11) vs. 23.5% (4/17)
        - RR 1.93; 95% CI, 0.66 to 5.65
    - These data were extracted by Zaina 2016 and reported as:
      - 3 months: 15.4% (2/13) vs. 11.1% (2/18)
        - RR 1.38; 95% CI, 0.22 to 8.59
      - 4 years: 41.7% (5/12) vs. 5.6% (1/18)
        - RR 7.5; 95% CI, 1 to 56.48
      - 10 years: 45.5% (5/11) vs. 11.1% (2/18)
        - RR 4.09; 95% CI, 0.95 to 17.58
    - Either way the data is analyzed there are no significant differences between groups at any time.

BHAT 2005

Bhat AL, Chow DW, DePalma MJ, et al. Incidence of vocal cord dysfunction after fluoroscopically guided steroid injections in the axial skeleton. Arch Phys Med Rehabil. 2005 Jul;86(7):1330-1332. PubMed
Relevant to FAQ3

- **Study design:** prospective cohort study
- **Population:** 100 patients (mean age 48 years, 52% female)

- **Intervention:** fluoroscopically guided therapeutic epidural injection (with 1% lidocaine plus betamethasone)
    - 62 lumbar selective nerve root injections (SNRIs) or transforaminal epidural injections (TFEIs) (12 mg of betamethasone)
    - 29 cervical SNRIs or TFEIs (6 mg)
    - 6 lumbar zygapophyseal joint injections (4.8 mg)
    - 3 sacroiliac joint injections (12 mg)
- **Comparison:** 2% lidocaine injection (performed prior to the steroid injection in all patients)
- **Outcomes:** dysphonia or associated throat symptoms
- **Duration of follow-up:** 7 days for all but 1 patient
    - 1 patient with persistent symptoms after 1 week was questioned again the following week
- **Certainty: High**
    - **Risk of bias:** Cohort study. Very small samples for some injection sites. 9 patients "did not undergo epidural deposition of steroid" but the authors did not explain why this happened or how it might have affected the findings.
    - **Precision:** No serious concerns
    - **Directness:** Findings may not be generalizable to older patients or to protocols other than those studied.
    - **Consistency:** No serious concerns
    - **Other considerations:** Findings supported objectively as 25% of patients had imaging to confirm edema. Higher certainty established by all-or-none response.
- **Results:**
    - 12 patients (8 lumbar SNRI, 4 cervical SNRI) developed dysphonia or other throat symptoms after epidural corticosteroid injection; none had such symptoms after diagnostic injection
    - Symptoms noted at 24 hours in 9 patients, 72 hours in 3 patients
    - Symptoms were transient and resolved within 1 week in 11 patients
    - 3 patients had vocal cord edema confirmed on imaging

BOTWIN 2000

Botwin KP, Gruber RD, Bouchlas CG, Torres-Ramos FM, Freeman TL, Slaten WK. Complications of fluoroscopically guided transforaminal lumbar epidural injections. Arch Phys Med Rehabil. 2000 Aug;81(8):1045-1050. PubMed

Relevant to FAQ3, FAQ4

- **Study design:** retrospective cohort study
- **Population:** 207 patients with radicular pain from either herniated nucleus pulposus (42 patients: mean age 38 years, 60% male, mean pain duration 6 months) or lumbar spinal stenosis (165 patients: mean age 72 years, 56% male, mean pain duration 43 months)
- **Intervention:** fluoroscopically guided lumbar transforaminal epidural injection of betamethasone (165 injections) or methylprednisolone (157 injections)
    - Patients received between 1 and 3 injections (average 1.6 injections per patient)
- **Comparison:** None
- **Outcomes:**
    - 24 hours after injection, patients were asked if they had any rash (discoloration of the skin), fever, increased pain, positional headache, nausea, vomiting, or other complaints.
    - They were also asked to estimate any change in their baseline pain level on a scale of ''much better,'' ''better,'' ''same,'' or ''worse.'' (findings not reported in this study)

- **Duration of follow-up:** Primary follow-up (by telephone) was at 24 hours after injection; physician follow-up visit occurred 1-3 weeks after injection
- **Certainty: Low**
  - **Risk of bias:** Retrospective cohort study
  - **Precision:** Confidence intervals were not reported
  - **Directness:** Also investigated patients with herniated nucleus pulposus as cause of symptoms; results reported here are limited to those with spinal stenosis
  - **Consistency:** No serious concerns
- **Results:**
  - incidence of side effects 8.8% per epidural injection in patients with spinal stenosis
    - nonpositional headaches (resolving within 24 hours) in 2.7%
    - increased back pain at injection site (resolving in 24 hours) in 1.9%
    - increased leg pain in 0.4%
    - facial flushing in 1.2%
    - vasovagal reaction in 0.4%
    - rash in 0.4%
    - leg weakness in 0.4%
    - dizziness in 0.4%
    - increased blood sugar (258 mg/dL) in an insulin-dependent diabetic in 0.4%
    - intraoperative hypertension in 0.4%
    - nausea in 0.4%

BOTWIN 2001

Botwin KP, Gruber RD, Bouchlas CG, et al. Complications of fluoroscopically guided caudal epidural injections. Am J Phys Med Rehabil. 2001 Jun;80(6):416-424. PubMed

Relevant to FAQ3, FAQ4

- **Study design:** retrospective cohort study
- **Population:** 139 patients (mean age 64 years, 58% female) with lumbosacral radiculopathy due to herniated disk or spinal stenosis (diagnosis-specific subgroups were not described or analyzed separately)
- **Intervention:** fluoroscopically guided caudal epidural injection of 18 to 28 mL of lidocaine plus 12 mg betamethasone acetate (120 injections)
- **Comparison:** fluoroscopically guided caudal epidural injection of 18 to 28 mL of lidocaine plus 80 mg triamcinolone acetonide (137 injections)
- **Outcomes:** complications self-reported by patients 24 hours after injection and/or in physician notes at follow-up visit 1-3 weeks later
- **Duration of follow-up:** up to 3 weeks
- **Certainty: Low**
  - **Risk of bias:** Retrospective cohort study.
  - **Precision:** Power calculations and confidence intervals were not reported.
  - **Directness:** Findings may not be generalizable to types and doses of steroids and injection techniques other than those studied.
  - **Consistency:** No serious concerns.
- **Results:**
  - incidence of side effects 15.6% per epidural injection
    - insomnia in 4.7%
    - nonpositional headaches (resolving within 24 hours) in 3.5%

- increased back pain at injection site (resolving in 24 hours) in 3.1%
- facial flushing in 2.3%
- vasovagal reaction in 0.8%
- nausea in 0.8%
- increased leg pain in 0.4%

BROWN 2012

Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the MILD procedure in patients with symptomatic lumbar spinal stenosis. Pain Pract. 2012 Jun;12(5):333-341. PubMed

Relevant to FAQ2c

- **Study design:** randomized trial
- **Population:** 38 adults (mean age 76 years, 55% male) with lumbar spinal stenosis and neurogenic claudication
- **Intervention:** MILD (minimally invasive lumbar decompression: percutaneous removal of small portions of lamina and selective tissue debulking under fluoroscopic guidance)
  - Patients continued with conservative medical management after surgery (specifics not given)
- **Comparison:** fluoroscopically guided epidural injection of 80 mg triamcinolone acetate (40 mg in patients with diabetes) mixed with 6 mL of saline
  - 100% of epidural group chose to cross over to surgical group after unblinding at 6 weeks
- **Outcome:**
  - pain (11-point visual analog scale)
  - disability (Oswestry Disability Index [ODI])
  - patient satisfaction (Zurich Claudication Questionnaire)
- **Duration of follow-up:** 12 weeks
- **Certainty: Low**
  - **Risk of bias:** Small sample size. Lack of no-treatment control. Blinding only maintained until 6-week follow-up; thereafter, patients were offered the opportunity to cross over, with 100% epidural injection patients crossing over to surgery, and not reported how many (or if any) surgery patients crossed over to receive epidural corticosteroid injections.
  - **Precision:** No serious concerns
  - **Directness:** No serious concerns. (However, this study does not represent the interventions and comparators [noninvasive control such as physical therapy] in the intended evidence review.)
  - **Consistency:** No serious concerns
- **Results:**
  - Pain
    - > 2-point improvement in VAS score in 35.3% of 17 patients after epidural steroid injection vs. 76.2% of 21 patients after decompression surgery at 6 weeks ($p < 0.01$)
    - mean pain score at 6 weeks after surgery vs. baseline
      - in 21 patients receiving early surgery 3.8 vs. 6.3 ($p < 0.01$)
      - in 14 patients receiving surgery after epidural steroid injection 4.5 vs. 7.4 ($p < 0.01$)
  - Disability (improvement from baseline; 0- to 100-point scale)
    - Surgical group: -11.4 points at 6 weeks, -18.6 points at 12 weeks

        - Epidural group: -5.7 points at 6 weeks
        - Improvement was statistically significant for surgical group but not for epidural group; significance of difference between groups was not reported
    - Patient satisfaction score of 2.5 or better (at least "somewhat satisfied") at week 6
        - Surgical group: 58.8%
        - Epidural group: 41.2%
    - Safety was comparable in both groups, with no deaths or major procedure-related or device-related complications in either group

CHOI 2013

Choi YS, Shim JK, Song JW, Kim JC, Yoo YC, Kwak YL. Combination of pregabalin and dexamethasone for postoperative pain and functional outcome in patients undergoing lumbar spinal surgery: a randomized placebo-controlled trial. Clin J Pain. 2013 Jan;29(1):9-14. PubMed
Relevant to FAQ3

- **Study design:** randomized trial
- **Population:** 120 patients (mean age 53 years, 44%-58% male, mean BMI 24 kg/m^2) with herniated lumbar disk or degenerative spinal stenosis having lumbar spinal surgery (49% laminectomy, 51% fusion)
    - Breakdown of herniated disk vs. spinal stenosis was not reported, nor were outcomes analyzed separately for different diagnoses
- **Intervention:** 36 patients had dexamethasone 16 mg injection prior to anesthesia induction plus oral pregabalin (150 mg every 12 hours, 8 total doses beginning 1 hour prior to anesthesia induction)
    - Anti-emetics were administered 20 minutes before the end of surgery
    - all patients had continuous infusion of fentanyl until 48 hours after surgery
    - patients were allowed to receive 30 mg ketorolac IV if they reported pain VAS pain ≥ 5
- **Comparisons:**
    - 36 patients had pregabalin 150 mg orally every 12 hours (total 8 doses) beginning 1 hour prior to anesthesia induction plus placebo (saline) injection
    - 36 patients had placebo injection and placebo capsules (18 patients had laminectomy and 18 had fusion)
    - anti-emetics were administered 20 minutes before the end of surgery
    - all patients had continuous infusion of fentanyl until 48 hours after surgery
    - patients allowed to receive 30 mg ketorolac IV if they reported pain VAS pain ≥ 5
- **Outcomes:**
    - Pain intensity, use of rescue analgesia, side effects assessed immediately post-surgery and at 12, 24, 48, and 72 hours
    - Pain intensity and daily activity level assessed at 1, 3, and 6 months
- **Duration of follow-up:** 72 hours for complications, 6 months for pain and activity
- **Certainty: Low**
    - **Risk of bias:** Relatively small sample size, particularly for analysis of secondary endpoints.
    - **Precision:** Confidence intervals were not reported, and sample sizes were small
    - **Directness:** Findings may not be generalizable to elderly patients, patients with obesity (those with BMIs > 35 kg/m^2 were excluded), or treatment protocols other than those studied.
    - **Consistency**: No serious concerns
- **Results:**

- median pain scores (visual analog scale 0-100, higher score indicating worse pain) in postoperative period in 36 patients receiving placebo
    - at rest
        - in postanesthesia care unit, score = 30
        - 12 hours after surgery, score = 20
        - 24-hour score = 30
        - 48-hour score = 10
        - 72-hour score = 10
        - 1-6 months, score = 0
    - with movement
        - 12 hours after surgery, score = 30
        - 24-hour score = 50
        - 48-hour score = 30
        - 72-hour score = 30
    - at work
        - 1-month score = 25
        - 3-month score = 0
        - 6-month score = 30
- rescue analgesic requirement during postoperative period among 36 patients receiving placebo
    - 50% during postanesthesia care unit- 12 hours
    - 25% during 12 - 24 hours
    - 36% during 24 - 48 hours
    - 8.3% during 48 - 72 hours
- among 36 patients having surgery, no back pain during daily activities
    - At 1 month in 19.4%
    - At 3 months in 36.1%
    - At 6 months in 66.6%
- Side effects
    - Patients using anti-emetic therapy for nausea and vomiting, by group
        - Placebo
            - 28% during postanesthesia care unit- 12 hours
            - 25% during 12 - 24 hours
            - 19% during 24 - 48 hours
            - 5% during 48 - 72 hours
        - Pregabalin plus placebo
            - 19% during postanesthesia care unit- 12 hours
            - 8% during 12 - 24 hours
            - 5% during 24 - 48 hours
            - 3% during 48 - 72 hours
        - Pregabalin plus dexamethasone
            - 17% during postanesthesia care unit- 12 hours
            - 5% during 12 - 24 hours
            - 10% during 24 - 48 hours
            - 5% during 48 - 72 hours
    - Other side effects: most commonly reported during 72 hours after surgery
        - Placebo: dizziness, headache, sedation
        - Pregabalin plus placebo: dizziness, sedation, headache

        - Pregabalin plus dexamethasone: dizziness, headache/sedation, blurred vision
        - No significant differences among groups
        - Rates were displayed graphically but specific percentages not reported. Highest rate (dizziness, pregabalin plus dexamethasone group) was about 13%

CHOU 2015

Chou R, Hashimoto R, Friedly J, et al. Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. Ann Intern Med. 2015 Sep 1;163(5):373-381. PubMed
Relevant to FAQ2b

- **Study design:** systematic review
- **Population:** 821 patients with spinal stenosis in 8 trials, and 2,912 patients with radiculopathy in 30 trials
    - For 8 spinal stenosis trials
        - mean age ranged from 45 to 75 years
        - duration of symptoms <3 months to 138 months
- **Intervention:** Epidural corticosteroid injection
- **Comparisons:** placebo interventions, different types/doses of corticosteroids, different injection techniques
- **Outcomes:** pain, function, composite outcomes, subsequent surgery, harms
- **Duration of follow-up:** 1 week to 3 years (6 weeks to 21 months for spinal stenosis)
- **Certainty: Low**
    - **Risk of bias:**
        - Risk of bias in underlying trials: Of spinal stenosis trials, 1 rated as good quality, 4 fair quality, and 3 poor quality. Methodological shortcomings included failure to report adequate randomization or allocation concealment methods; inadequate blinding of outcome assessors, injectionists, or patients; high or unclearly reported attrition; and failure to specify primary outcomes.
        - Potential biases or limitations in review conduct and reporting:
            - concerns about meta-analysis, including:
                - trial with no placebo control (Koc 2009) was included in pooled analysis comparing epidural corticosteroid injections vs. placebo;
                - trial reporting composite outcome (Fukusaki 1998) was excluded from pooled analysis on “Successful composite outcome”
            - key risk of bias domains (eg, random sequence generation, allocation concealment) were not reported for included trials and only an overall assessment of “Quality” of trials was reported, as “good”, “fair” or “poor”
    - **Precision:** No serious concerns
    - **Directness:** No serious concerns.
    - **Consistency:** Some heterogeneity reported for function outcomes at short-term follow-up.
- **Results:**
    - in patients with spinal stenosis, epidural corticosteroids associated with

        - improvement in pain at 2 weeks in 1 trial with 29 patients (weighted mean difference in pain score -22, 95% CI -36 to -8) (vs. home exercise or inpatient physical therapy)
        - no significant improvement in pain (vs. placebo interventions)
            - at short-term follow-up of 2 weeks to ≤ 3 months in pooled analysis of 5 trials with 615 patients
            - at intermediate-term follow-up of 3 months to < 1 year in pooled analysis of 3 trials with 179 patients
        - significantly increased walking distance at 1 week in 1 trial with 53 patients (vs. placebo interventions)
        - improvement in function at 2 weeks in 1 trial with 29 patients (vs. home exercise or inpatient physical therapy)
        - no improvement in function at follow-up of 2 weeks to ≤ 3 months in pooled analysis of 5 trials with 615 patients (vs. placebo interventions)

DELITTO 2015

Delitto A, Piva SR, Moore CG, et al. Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial. Ann Intern Med. 2015 Apr 7;162(7):465-473. PubMed
Relevant to FAQ2a, FAQ2c, FAQ4

- **Study design:** randomized trial
- **Population:** 169 adults with symptomatic lumbar spinal stenosis
    - Surgery group: 87 patients (mean age 67 years, 51% male, 95% white, mean BMI 32 kg/m^2, 95% inactive or mildly active)
    - Physical therapy group: 82 patients (mean age 70 years, 54% male, 94% white, mean BMI 31 kg/m^2, 90% inactive or mildly active)
- **Intervention:** surgical decompression
    - Included decompressive laminectomy, partial facet resection, and neuroforaminotomy at the level of radiographic stenosis
    - Did not include spinal fusion
    - Recovery included graduated ambulation program beginning on postoperative day 1
    - 2/87 patients randomized to surgery crossed over to physical therapy group before 10-weeks
- **Comparison:** 6 weeks of physical therapy (2 visits per week) focused on lumbar flexion, general conditioning exercises, and patient education
    - mean number of sessions 8.4
    - 47/82 (57%) of those randomized to physical therapy crossed over to surgery during study period
        - Of these, 79% had attended at least 1 physical therapy session (mean 7.8 sessions)
        - 66% crossed over to surgery prior to 10 weeks (mean of 7.5 physical therapy visits; 74% having at least one physical therapy session)
- **Outcome:** physical function
- **Duration of follow-up:** 24 months
- **Certainty: Low** for comparative efficacy; **Moderate** for prognostic consideration
    - **Risk of bias:** No blinding.
    - **Precision:** Wide confidence intervals
    - **Directness:** No serious concerns.

- **Consistency:** No serious concerns
- **Other considerations:** High rate of crossover (57%) from physical therapy group to surgery group. However, as-treated analyses, intention-to-treat analyses, and additional analyses specifically designed to evaluate for impact of crossovers all have similar findings which mitigate the influence on certainty from the crossover rate.

- **Results:**
  - physical function by various measures improved in both groups compared to baseline at 10 weeks, 26 weeks, 52 weeks, and 104 weeks
    - Complier average causal effect (CACE) and inverse probability weighting (IPW) analyses, designed to account for the high rate of crossovers in the physical therapy group, also found no significant difference between groups
  - no significant differences in function scores at any time comparing surgery vs. physical therapy
  - physical function score (on a 0 to 100 scale) improved from mean about 25-30 before treatment to about 40-50 after treatment
  - successful outcome at 2 years (improvement >0.5 SD relative to baseline) was not clearly different between those randomized to surgery and those randomized to physical therapy (for whom data were available)
    - Rate for those randomized to surgery for whom data were available: 61% (45/74)
    - Rate for those randomized to physical therapy for whom data were available: 53% (39/73)
      - Patients who crossed over to surgery: 55% (24/44)
      - Patients who did not cross over to surgery: 52% (15/29)
    - Absolute risk difference of 7.4% (95% CI, -8.4% to 22.7%) – Note the risk difference and CI were not reported in the trial itself and were thus calculated for this report
  - "Complications" reported with limited detail and assignments as "surgery-related", "physical therapy-related" and "other" without explanations as how these determinations were made
    - "Worsening symptoms" were more commonly reported with physical therapy under "PT-related" (8 PT patients vs. 1 surgery patient), but "Worsening symptoms" were also reported for 7 patients under "Other clinical complications" in the surgery group
    - Deaths reported in 4 surgery patients and 2 physical therapy patients, but none were attributed to surgery-related or physical therapy-related
    - Surgery-related complications reported in
      - 22/87 in patients randomized to surgery (25%)
      - 11/82 in patients randomized to physical therapy (13%)
      - Most common
        - Reoperation (3%/7%)
        - Wound healing/site infection (8%/2%)
        - Other surgery (6%/0%)
        - Worsening symptoms (2%/2%)
        - Respiratory tract infection or other illness (3%/1%)

DYNAMED PLUS 2018

DynaMed Plus. Epidural steroid injection. DynaMed Plus website. https://www.dynamed.com/topics/dmp~AN~T901362/Epidural-steroid-injection. Accessed Oct 26, 2018.

DynaMed Plus. Lumbar spinal stenosis. DynaMed Plus website. https://www.dynamed.com/topics/dmp~AN~T114133/Lumbar-spinal-stenosis. Accessed Oct 26, 2018.
Relevant to FAQ1

- General reference used as source for studies

EBSCO HEALTH LIBRARY 2018

EBSCO Health Library. Spinal corticosteroid injection. EBSCO Health Library website. http://healthlibrary.epnet.com/GetContent.aspx?token=D39207C8-9100-4DC0-9027-9AC6BA11942D&chunkiid=112171. Accessed Oct 26, 2018.
Relevant to FAQ1

- General reference used for generic information on epidural steroid injection
    - What it involves
        - corticosteroids are injected into the epidural space around the spinal nerve roots of the lumbar portion of the spine to relieve pain or inflammation
        - the procedure can be performed in a hospital or outpatient facility and takes about 30-60 minutes; your recovery will be monitored after the injection
        - anesthesia is not required, may be used if needed
        - temporary pain at site of injection may occur and usually treated by applying ice pack
    - Postprocedure care
        - At the care center
            - You will spend time in a recovery area where your recovery will be monitored.
            - Because you were sedated during the procedure, you will need someone to drive you home.
            - Potential temporary side effects include:
                - Brief period of increased pain
                - Headaches
                - Trouble sleeping
                - Facial flushing
                - Hiccups
                - Lightheadedness from low blood pressure
        - At home
            - When you return home after the procedure, do the following to help ensure a smooth recovery:
                - Rest on the day of the procedure.
                - Apply ice packs for soreness at the injection site.
                - It will take a few days to a week for the medication to reduce the inflammation and pain. You should be able to resume your

regular activities the day after the procedure. You should be able to start exercising within 1 week.

EL ABD 2015

El Abd O, Amadera J, Pimentel DC, Gomba L. Immediate and acute adverse effects following transforaminal epidural steroid injections with dexamethasone. Pain Physician. 2015 May-Jun;18(3):277-86. PubMed

Relevant to FAQ3, FAQ4

- **Study design:** prospective observational study
- **Population:** 150 consecutive patients having transforaminal epidural steroid injections with dexamethasone for managing radicular and axial spinal pain at the cervical, lumbar, and sacral levels; 122 had lumbar injections
- **Intervention:** fluoroscopically guided transforaminal epidural steroid injections with dexamethasone
- **Outcomes:** adverse events
- **Duration of follow-up:** 2-week time period after injection
- **Certainty: Low** because results not reported specific to lumbar injections
- **Results**:
    - proportion with side effects
        - 20.7% immediately after injection, with most common being
            - numbness in 10%
            - tingling in 2.7%
            - pruritus (genital, perineal, groin area) in 4.7%
        - 47.3% at 1 day after injection - most commonly injection site pain (17%), headaches (14%), insomnia (14%), increased radicular pain (9%), rash/flush (4%)
        - 13.3% at 3 days after injection – mostly increased radicular pain
        - 1.3% at 2 weeks after injection
    - all side effects were transient and minor, and no major complications were reported

EVERETT 2004

Everett CR, Baskin MN, Speech D, Novoseletsky D, Patel R. Flushing as a side effect following lumbar transforaminal epidural steroid injection. Pain Physician. 2004 Oct;7(4):427-429. PubMed

Relevant to FAQ3

- **Study design:** prospective cohort study
- **Population:** 240 patients with radicular pain (specific diagnoses not specified)
- **Intervention:** fluoroscopically guided transforaminal epidural injection of 6 mg betamethasone acetate/betamethasone sodium phosphate (81 patients)
- **Comparison:** fluoroscopically guided transforaminal epidural injection of 80 mg methylprednisolone (159 patients)
- **Outcome(s):** presence/absence of flushing (defined as redness or warmth, without rash) within 2 days of injection
- **Duration of follow-up:** 2 days
- **Certainty: Low**
    - **Risk of bias:** Flushing was self-reported two days after the procedure, subject to patient recall and possibility of misidentification.
    - **Precision:** No serious concerns.

    - **Directness:** No serious concerns.
    - **Consistency:** Incidence of flushing varied with steroids.
- **Results:**
    - Incidence of flushing
        - Methylprednisolone 9%
        - Betamethasone 16%
        - Total 11%

FRIEDLY 2014

Friedly JL, Comstock BA, Turner JA, et al. A randomized trial of epidural glucocorticoid injections for spinal stenosis. N Engl J Med. 2014 Jul 3;371(1):11-21. PubMed [6 weeks of follow-up]

Friedly JL, Comstock BA, Turner JA, et al. Long-term effects of repeated injections of local anesthetic with or without corticosteroid for lumbar spinal stenosis: a randomized trial. Arch Phys Med Rehabil. 2017 Aug;98(8):1499-1507. PubMed [1 year of follow-up]
Relevant to FAQ2b, FAQ3, FAQ4

- **Study design:** randomized trial
- **Population:** 400 patients ≥ 50 years old (mean age 68 years, 69% white, 52%-58% female) with lumbar central spinal stenosis plus moderate-to-severe leg pain and disability
- **Intervention:** 1-2 fluoroscopically guided epidural injections of steroid plus lidocaine
    - 143 patients received interlaminar injections, 57 had transforaminal
    - Steroids used: triamcinolone 21.5%, betamethasone 31%, dexamethasone 17%, methylprednisolone 30.5%
- **Comparison:** 1-2 fluoroscopically guided epidural injections of lidocaine alone
    - 139 patients received interlaminar injections, 61 had transforaminal
- **Outcomes:** pain, disability, adverse events
- **Results at duration of follow-up:** 6 weeks [Friedly 2014]
    - **Certainty: Moderate**
        - **Risk of bias:** Baseline differences in duration of pain before randomization (p = 0.02), which may influence statistical significance of disability score changes in adjusted analysis
        - **Precision:** No serious concerns
        - **Directness:** No serious concerns
        - **Consistency:** No serious concerns
        - **Other considerations:** Outcome measures at 3 weeks are compatible with a small differential effect for the steroid while later outcome measures suggest little to no additional efficacy (at 6 weeks, 12 weeks, 6 months and 1 year).
    - Disability (Roland-Morris Disability Questionnaire)
        - Mean change at 3 weeks -4.4 with steroid, -2.6 with lidocaine (group difference -1.8, p < 0.001)
        - Mean change at 6 weeks -4.2 with steroid, -3.1 with lidocaine (group difference -1.0, p = 0.07)
        - 30% improvement at 6 weeks: 37% of steroid group, 32% of lidocaine group (not significant)
        - 50% improvement at 6 weeks: 24% of steroid group, 20% of lidocaine group (not significant)

- Pain
  - Mean change at 3 weeks -2.9 with steroid, -2.2 with lidocaine (group difference -0.6, p = 0.02)
  - Mean change at 6 weeks -2.8 with steroid, -2.6 with lidocaine (group difference -0.2, not significant)
  - 30% improvement at 6 weeks: 49% of steroid group, 50% of lidocaine group (not significant)
  - 50% improvement at 6 weeks: 38% of steroid group, 38% of lidocaine group (not significant)
- Proportion very or somewhat satisfied with treatment at 6 weeks: 67% of steroid group, 54% of lidocaine group (p = 0.01)
- Comparing adverse events in 200 patients receiving epidural injections of steroid plus lidocaine vs. 200 patients receiving lidocaine alone
  - any adverse event rate 21.5% vs. 15.5% (p = 0.08)
    - excessive pain (2.5% vs. 3.5%)
    - headache (4% vs. 1.5%)
    - fever and/or infection (5% vs. 1%)
    - dizziness and/or lightheadedness (2% in each group)
    - numbness/tingling (2.5% vs. 2%)
    - cardiovascular/lung problems (3% vs. 1%)
    - falls (2% vs. 1%)
    - facial flushing (1.5% vs. 0%)
    - skin irritation (1% vs. 2%)
    - leg swelling (1% vs. 0.5%)
    - dural puncture (0.5% vs. 0.5%)
    - other events (5.5% vs. 2%)
  - any adverse event rate considered by investigators to be treatment-related 15% vs. 9.5% (p = 0.09)
  - serious adverse event requiring hospitalization and/or surgery in 5 (2.5%) vs. 4 (2%)
  - serious adverse event requiring hospitalization and/or surgery considered by investigators to be treatment-related 0% vs. 0.5%

- **Results at duration of follow-up:** 1-year follow-up [Friedly 2017]
  - **Certainty: Low** (for outcomes after 6 weeks)
    - **Risk of bias:** Baseline differences in duration of pain before randomization (p = 0.02). High rates of crossover from nested study design may reduce ability to detect differences at 1 year.
    - **Precision:** No serious concerns.
    - **Directness:** No serious concerns.
    - **Consistency:** No serious concerns.
    - **Other considerations:** Within-trial study of crossover to opposite treatment (weeks 6-12) selected by 30% steroid group and 45% lidocaine group failed to find between-group differences at 12 weeks.
  - Patients available for follow up
    - 12 weeks: 185 randomized to corticosteroid, 186 randomized to lidocaine alone
    - 6 months: 182 randomized to corticosteroid, 177 randomized to lidocaine
    - 1 year: 180 randomized to corticosteroid, 174 randomized to lidocaine

- ITT analysis
  - Disability
    - Scores over time (corticosteroid vs. lidocaine alone)
      - Baseline: 16 vs. 15.6 (p=0.33)
      - 3 weeks: 11.7 vs. 13.1 (p<0.001)
      - 6 weeks: 11.8 vs. 12.5 (p=0.03)
      - 12 weeks: 12 vs. 11.2 (p=0.84)
      - 6 months: 12.2 vs. 11.4 (p=0.99)
      - 1 year: 12 vs. 11.5 (p=0.55)
    - 50% improvement from baseline at 12 months
      - 46 of 180 patients in corticosteroid group (26%)
      - 48 of 174 patients in lidocaine only group (28%)
      - No significant difference between groups (p=0.33)
  - Pain
    - Scores over time (corticosteroid vs. lidocaine alone)
      - Baseline: 7.2 vs. 7.2 (p=0.96)
      - 3 weeks: 4.4 vs. 5 (p=0.01)
      - 6 weeks: 4.4 vs. 4.6 (p=0.32)
      - 12 weeks: 4.6 vs. 4.3 (p=0.7)
      - 6 months: 4.5 vs. 4.5 (p=0.47)
      - 1 year: 4.7 vs. 4.3 (p=0.75)
    - 50% improvement from baseline at 12 months
      - 37% in corticosteroid group
      - 47% in lidocaine only group
      - No significant difference between groups (p=0.07)
  - Long-term outcomes (specific data not provided)
    - In both randomization groups, patients who crossed over at 6 weeks continued to have worse outcomes at 6 months and 1 year compared with those who repeated the randomized injection or had no additional injections
    - No significant difference in 1-year pain or function between those who crossed over to corticosteroid injection vs. those who crossed over to lidocaine injection
- Rates of spine surgery at 1 year
  - 17% of patients randomized to corticosteroid
  - 12% of patients randomized to lidocaine alone
  - p=0.22
- Opioid use at 1 year
  - 41% of patients randomized to corticosteroid
  - 36% of patients randomized to lidocaine alone
  - p=0.41

GERBERSHAGEN 2013

Gerbershagen HJ, Aduckathil S, van Wijck AJ, Peelen LM, Kalkman CJ, Meissner W. Pain intensity on the first day after surgery: a prospective cohort study comparing 179 surgical procedures. Anesthesiology. 2013 Apr;118(4):934-944. PubMed

Relevant to FAQ3

- **Study design:** cohort study
- **Population:** 50,523 adults (55% female, 77% evenly distributed between ages 41 and 80) in German hospitals reported pain intensity (scale 0-10 with higher score indicating worse pain) on day 1 after any of 179 surgical procedures
    - 1,702 patients underwent spinal decompression, fusion, or laminectomy
    - underlying diagnoses were not reported
    - affected spinal region (lumbar, thoracic, cervical) specified only for laminectomy
- **Intervention:** 179 types of surgical procedures related to obstetrics (881 patients), orthopedics/traumatology (30,823), general/abdominal surgery (13,696), neurosurgery (1,234), cardiothoracic surgery (525), gynecology (4,871), ear/nose/throat surgery (1,929), general/nonabdominal surgery (10,603), oral/maxillofacial surgery (542), vascular surgery (3,003), and eye surgery (104)
- **Comparisons:** pain outcomes for each procedure and related surgical group were compared to the others
- **Outcomes:** worst pain intensity since surgery, pain reported on 0-10 scale
- **Duration of follow-up:** 1 day
- **Certainty: Low**
    - **Risk of bias:** Selection/volunteer bias: hospitals volunteering to participate may be working more actively to improve postoperative pain management than those that did not participate (could lead to underestimation of inadequate pain relief). Procedures and protocols not standardized among participating hospitals. Pain scores were intentionally not adjusted for risk factors.
    - **Precision:** No serious concerns
    - **Directness:** Findings may not be generalizable to countries other than Germany
    - **Consistency:** No serious concerns
- **Results:** Spinal fusion surgeries ranked higher than many other procedures for pain severity after surgery.

Spinal procedure	Number of patients having the procedure	Mean pain score	% of patients with pain score ≥ 6	% of patients with pain score ≥ 8
Spinal fusion (dorsal 1-2 segments)	126	6.61	72.2%	45.2%
Spinal fusion (dorsal ≥ 3 segments)	40	6.55	62.5%	45%
Spinal fusion (ventral 1-2 segments)	95	5.03	44.1%	21%
Spinal canal decompression (2 segments)	167	4.77	36.6%	18.6%
Spinal canal decompression (1 segment)	407	4.7	35.4%	14.7%
Lumbar laminectomy	867	4.53	31.6%	16.6%

  - median pain scores in patients receiving general anesthesia for spinal fusion or decompression surgeries ranged from 4 to 7
  - opioid consumption (calculated as morphine equivalent) after spinal surgeries ranged from 19 mg to 38 mg

GUHA 2015

Guha D, Heary RF, Shamji MF. Iatrogenic spondylolisthesis following laminectomy for degenerative lumbar stenosis: systematic review and current concepts. Neurosurg Focus. 2015 Oct;39(4):E9. PubMed
Relevant to FAQ4

- **Study design:** systematic review of cohort studies
- **Population:** 2,496 patients with degenerative lumbar stenosis, either with or without spondylolisthesis, from 24 surgical cohorts
- **Intervention:** laminectomy or minimally invasive decompression without fusion
- **Outcomes:** reoperation for instability
- **Certainty: Moderate** (heterogeneity not assessed for pooling)
- **Results:**
  - postoperative instability
    - 5.5% overall
    - higher in patients with preexisting spondylolisthesis (12.6%) and in patients treated with open laminectomy (12%)

- reoperation for instability
  - 1.8% overall
  - higher in patients with preexisting spondylolisthesis (9.3%) and in patients treated with open laminectomy (4.1%)

HARRIS 2012

Harris IA, Dantanarayana N, Naylor JM. Spine surgery outcomes in a workers' compensation cohort. ANZ J Surg. 2012 Sep;82(9):625-629. PubMed

Relevant to FAQ5

- **Study design:** retrospective cohort study
- **Population:** 476 patients (mean age 41 years, 77% male) undergoing lumbar spine surgery and receiving workers' compensation
- **Intervention:** decompression (72.8% of patients)
- **Comparison:** decompression and fusion (19.4% of patients)
- **Outcomes:**
  - return to work rate at 2 years
  - return to preinjury duties at 2 years
  - revision surgery rates at 2 years
- **Duration of follow-up:** 2 years
- **Certainty: Low**
  - **Risk of bias:** Cohort study design. Data came from a third party with nonclinical objectives, and outcomes may have been incomplete (e.g., if claims were settled).
  - **Precision:** Confidence intervals were not reported
  - **Directness:** Limited to New South Wales, Australia. Findings may not be generalizable to women, older patients, nonworkers' compensation patients, or surgical protocols other than those studied.
  - **Consistency:** No serious concerns.
- **Results:**
  - revision surgery at 24 months after primary surgery
    - 9.2% overall
    - 9.8% for decompression
    - 6.5% for fusion
  - return to any work at 24 months after surgery
    - in 50.3% overall
    - in 55.1% of patients having decompression
    - in 36.3% of patients having fusion
  - return to pre-injury duty 24 months after surgery
    - in 14.2% overall
    - in 17.3% of patients having decompression
    - in 3.3% of patients having fusion

HERNO 1996

Herno A, Airaksinen O, Saari T, Svomalainen O. Pre- and postoperative factors associated with return to work following surgery for lumbar spinal stenosis. Am J Ind Med. 1996 Oct;30(4):473-8. PubMed

Relevant to FAQ5

- **Study design:** cohort study
- **Population:** 439 patients in Finland who had lumbar spinal stenosis surgery
- **Intervention:** lumbar spinal stenosis surgery
- **Outcomes:** return to work, and variables that predicted it
- **Certatinty: Low**
- **Results:**
    - return to work after operation
        - 37% of women
        - 41% of men
    - variables that predicted return to work in both men and women
        - being fit to work at time of operation
        - age < 50 at time of operation
    - no patient who had retired before operation returned to work after operation

KARAMAN 2011

Karaman H, Kavak GO, Tüfek A, Yldrm ZB. The complications of transforaminal lumbar epidural steroid injections. Spine (Phila Pa 1976). 2011 Jun;36(13):E819-24. PubMed
Relevant to FAQ3, FAQ4

- **Study design:** prospective cohort study
- **Population:** 562 with lumbar disc hernia accompanied by radiculopathy
- **Intervention:** transforaminal lumbar epidural steroid injections (1,305 injections in 562 patients) performed under fluoroscopic guidance by same physician using standardized approach
- **Comparison(s):** Not applicable
- **Outcomes:** complications during procedure and at 3 weeks follow-up
- **Duration of follow-up:** 3 weeks
- **Certainty**: Low
- **Results:**
    - no major complications observed
    - minor complications
        - overall incidence 11.5%
        - frequency of specific minor complications
            - vasovagal reaction characterized by hypotension, nausea, and dizziness in 8.7% of patients
            - transient erectile dysfunction in 1.9% of male patients
            - facial flushing in 0.9% of patients
    - vascular penetration
        - total rate of 7.4% (97 times in 1,305 procedures)
        - most commonly seen at levels of L2-L3 and L1-L2

KIM 2010

Kim CH, Issa MA, Vaglienti RM. Flushing following interlaminar lumbar epidural steroid injection with dexamethasone. Pain Physician. 2010 Sep-Oct;13(5):481-4. PubMed
Relevant to FAQ3

- **Study design:** retrospective cohort study
- **Population:** 150 patients with low back pain with radiculopathy who received epidural steroid injection

- **Intervention:** fluoroscopically guided interlaminar lumbar epidural steroid injection using dexamethasone 16 mg (4 mg/mL)
- **Comparison(s):** Not applicable
- **Outcomes:** frequency of flushing (yes/no), assessed following procedure on day of injection and at follow-up ≤ 48 hours after injection
- **Duration of follow-up:** 48 hours
- **Certainty**: Low
- **Results**: overall incidence of flushing 28%, all resolved within 48 hours

KRANZ 2015

Kranz PG, Amrhein TJ, Gray L. Incidence of Inadvertent Intravascular Injection during CT Fluoroscopy-Guided Epidural Steroid Injections. AJNR Am J Neuroradiol. 2015 May;36(5):1000-7. PubMed
Relevant to FAQ3, FAQ4

- **Study design:** retrospective cohort study
- **Population:** 575 consecutive CT fluoroscopy-guided epidural steroid injections
- **Intervention:** CT fluoroscopy-guided epidural steroid injections performed by single proceduralist
- **Outcomes:** intravascular injection based on double-reading of CT fluoroscopy images
- **Certainty**: Moderate
- **Results:** risk of intravascular injection
    - 8% for lumbar transforaminal epidural steroid injections (22/275)
    - 2% for lumbar interlaminar epidural steroid injections (4/222)

KREINER 2013

Kreiner DS, Shaffer WO, Baisden JL, et al; North American Spine Society. An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis (update). Spine J. 2013 Jul;13(7):734-743. PubMed
Relevant to FAQ1, FAQ2a, FAQ3

- This guideline is an update to an earlier guideline published in 2011 (Kreiner DS, Shaffer WO, Baisden JL, et al; North American Spine Society. Diagnosis and treatment of degenerative lumbar spinal stenosis. Evidence-based clinical guidelines for multidisciplinary spine care. North American Spine Society website. Available at: https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/LumbarStenosis.pdf?ver=2015-06-05-125420-320, systematic review and technical report with evidentiary tables available at: https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/LumbarStenosisTechReport.pdf?ver=2015-06-05-125446-897)
- Suggests considering nonsurgical treatment for patients with mild or moderate symptoms of lumbar spinal stenosis. Options include:
    - limited course of active physical therapy (insufficient evidence, work group consensus statement)
    - lumbosacral corset for improvement in walking distance and decreased pain while the corset is worn (Grade B recommendation, but based on two level III and one level IV study per their levels of evidence: https://www.spine.org/ResearchClinicalCare/Research/LevelsofEvidence)

- medications have insufficient evidence to recommend for or against use, but may include:
    - acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), although there is no evidence of benefit in patients with lumbar spinal stenosis
    - mild narcotic analgesics in patients who are unresponsive to or intolerant of NSAIDs
    - gabapentin

- The 2013 update also included a systematic review of case series that was carried out by Kreiner at al. and reported in the 2013 guideline they authored
    - **Study design:** systematic review of case series
    - **Population:** 350 patients in 4 studies
    - **Intervention:** medical/interventional treatment (includes physical therapy and exercise, massage, epidural steroid injections, oral medications, and multimodal nonoperative care)
    - **Comparisons:** surgical decompression or no comparison
    - **Outcomes:** pain (various measures used)
    - **Duration of follow-up:**
        - 2 years (2 studies)
        - 3 years (1 study)
        - 10 years (1 study)
    - **Certainty: Very low**
        - **Risk of bias:** Based on case series. Small sample sizes. No control groups. Significant heterogeneity of nonsurgical protocols among studies.
        - **Precision:** No serious concerns
        - **Directness:** Findings may not be generalizable to nonsurgical protocols other than those studied.
        - **Consistency:** Degree of pain improvement varied among studies, likely due in part to variability in treatment protocols and duration.
    - **Results:**
        - long term outcomes in patients receiving nonsurgical medical interventions based on 4 studies
            - 20% to 40% will require surgical intervention
            - 50%-70% of patients treated without surgery will have improvement in pain
        - 2 studies reported some improvement in function following nonoperative treatment at 2 years
            - 40% of 91 patients had some improvement in function in 1 study
            - 15% unable to walk 1,000 meters without claudication after nonoperative treatment vs. 72% before nonoperative treatment in 1 study with 82 patients
        - Adverse events
            - In 1 trial of prostaglandins vs. etodolac, 5% of participants in both groups had gastrointestinal upset
            - In 1 trial, some participants taking gabapentin (no data specified) had mild to moderate dizziness, drowsiness, or both
            - In 6 trials of calcitonin, minor adverse effects (including nausea and rash) were reported in 40% to 89% of participants

- In 2 trials of physical therapy, 1 patient reported a mild increase in symptoms with exercises, and 1 experienced angina pectoris

LEE 2017

Lee S, Kim CH, Chung CK, et al. Risk factor analysis for postoperative urinary retention after surgery for degenerative lumbar spinal stenosis. Spine J. 2017 Apr;17(4):469-477. PubMed
Relevant to FAQ4

- **Study design:** retrospective cohort study
- **Population:** 284 patients (mean age 63 years, 56% female) with degenerative lumbar spinal stenosis and no history of voiding difficulty before surgery
- **Intervention:** surgery (54% decompression only, 46% decompression plus fusion)
    - urinary catheter inserted during surgery was removed in postanesthesia care unit
    - patients encouraged to urinate within 6 hours postop and every 4-6 hours after that
- **Comparison:** none
- **Outcome:** postoperative urinary retention
    - defined as inability to urinate or having a postvoid residual urine (determined using ultrasound) ≥100 ml for more than 2 days after surgery
- **Duration of follow-up:** 2 days
- **Certainty: Low**
    - **Risk of bias:** Retrospective design. Single-center study. Use of catheterization could have caused urethral irritation or otherwise affected incidence of postoperative urinary retention. Possible selection bias due to incomplete data in some otherwise eligible patients.
    - **Precision:** No serious concerns
    - **Directness:** Findings may not be generalizable to simple decompression surgery in real-world practice, or other lumbar spine surgeries that do not typically involve catheterization. Findings may not be generalizable to patients with a history of urinary issues, who were excluded, or patients who are not Korean.
    - **Consistency:** No serious concerns
- **Results:**
    - Incidence of postoperative urinary retention: 27.1%
        - Other adverse events: Motor deficits associated with nerve root injury during surgery in 3.2% of patients
    - Older age (OR 1.062, 95% CI 1.029-1.095) and longer duration of surgery (OR 1.003, 95% CI 1.001-1.005) were significant independent risk factors for postoperative urinary retention

LIU 2015

Liu K, Liu P, Liu R, Wu X, Cai M. Steroid for epidural injection in spinal stenosis: a systematic review and meta-analysis. Drug Des Devel Ther. 2015 Jan 30;9:707-16. PubMed
Relevant to FAQ2b

- **Study design:** systematic review of randomized trials
- **Population:** inclusion limited to patients with lumbar spinal stenosis
- **Intervention:** epidural injections of steroids plus local anesthetic

- **Comparison(s):** epidural injections of local anesthetic alone
- **Outcomes:** primary outcomes reported were patient-rated pain and walking ability
- **Duration of follow-up:** varied, trial with longest duration of follow-up (Manchikanti 2012) reported follow-up of 2 years
- **Certainty: Unusable**
    - Because of concerns about this review's methods and the limited usefulness of the reported results, as described here, we did not use it for outcome data extraction or for an assessment of the quality and strength of the underlying trial evidence.
        - reported to include only randomized controlled trials (which implies data comparing randomized groups), but 1 included study was a cohort analysis of epidural use data from the SPORT randomized trial (Radcliff 2013) where the randomization was about surgery vs. conservative therapy
        - includes inaccurate assessments of risk of bias of included trials:
            - Results text states "All of the studies were RCTs with a high level of methodological quality.", and refers to the Risk of Bias Figure which shows that only 1 trial had low risk of bias for all domains, most trials had multiple risks of bias, and 3 trials had high or unclear risk of bias for all domains
            - Risk of Bias figure provides inaccurate assessments, for example it reports that Koc 2009 had low risk of bias for patient blinding domain but this trial had no placebo group and no patient blinding
        - patients with radiculopathy caused by disc lesions were reported to be excluded (according to Methods/Study selection) but 1 included trial (Ng 2005) was in patients with lumbar disc herniation
        - pooled effect estimates were reported for various outcomes at various time points but there was no reporting of which trials were included in each pooled analysis

MA 2017

Ma XL, Zhao XW, Ma JX, Li F, Wang Y, Lu B. Effectiveness of surgery versus conservative treatment for lumbar spinal stenosis: A system review and meta-analysis of randomized controlled trials. Int J Surg. 2017 Aug;44:329-338. PubMed

Relevant to FAQ2c

- **Study design:** systematic review of randomized trials
- **Population:** trials of patients with lumbar spinal stenosis were included (although Methods section did not report patient inclusion criteria)
- **Intervention:** surgery (assumedly any type, Methods reported intervention inclusion criteria only as "surgery")
- **Comparison(s):** conservative treatment (assumedly any type, Methods reported control inclusion criteria only as "conservative treatment")
- **Outcomes:** Methods section did not report which outcomes would be evaluated, but Results section reported outcomes for function and pain
- **Duration of follow-up:** varied, trial with longest duration of follow-up (Amundsen 2000) reported 10 years of follow-up
- **Certainty: Unusable**

- Because of concerns about this review's methods and the limited usefulness of the reported results, as described here, we did not use it for outcome data extraction or for an assessment of the quality and strength of the underlying trial evidence.
    - 2 studies were included that do not appear to be randomized trials based on their PubMed abstracts (Puzzilli 2014 {25064150}; Mariconda 2002 {11891449}); neither was included in the Cochrane review on this topic (CD010264), with Mariconda 2002 being excluded (because of not having random assignment), and Puzzilli 2014 not being mentioned
    - Risk of bias assessments were unreliable for included trials; for example, 2 trials (Benyamin 2016; Delitto 2015) were judged by review authors to have low risk of bias for patient blinding domain but neither of these trials used patient blinding
    - Trials were not considered clinically appropriate for pooled analysis; for example, a trial comparing surgery vs. epidural steroid injection (Benyamin 2016) was pooled with trials comparing surgery vs. physical therapy
    - Trials were meta-analyzed separately if they reported the same outcome on a different measurement scale, which resulted in a given meta-analysis including only a subset of all available trials (eg, trials that reported function using Oswestry scale were meta-analyzed separately from trials that reported function using SF-36 physical function scores).

MALMIVAARA 2007

Malmivaara A, Slätis P, Heliovaara M, et al; Finnish Lumbar Spinal Research Group. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. Spine. 2007 Jan 1;32(1):1-8. PubMed [2 years of follow-up]

Slätis P, Malmivaara A, Heliovaara M, et al. Long-term results of surgery for lumbar spinal stenosis: a randomized controlled trial. Eur Spine J. 2011 Jul;20(7):1174-1181. PubMed [6 years of follow-up]

Relevant to FAQ2a, FAQ2c

- **Study design:** randomized trial
- **Population:** 94 patients with lumbar spinal stenosis (with or without instability)
    - Surgical group**:** 50 patients (mean age 63 years, 78% female, mean body mass index (BMI) 27 kg/m^2, pain during 80% of days in the past month)
    - Nonsurgical group**:** 44 patients (mean age 62 years, 55% female, mean BMI 28 kg/m^2, pain during 74% of days in the past month)
- **Intervention:** surgery (segmental decompression and an undercutting facetectomy in all patients, plus fusion as needed for instability in 10 patients)
- **Comparison:** nonsurgical treatment
    - NSAIDs
    - 1 to 3 physical therapy visits
    - Additional active or passive treatment provided in 10 patients (24%)
- **Outcomes:**
    - disability (Oswestry Disability Index on 0-100 scale)
    - back pain and leg pain (numerical rating scale 0-10)
    - walking ability
        - measured in Malmivaraa 2007 as self-reported and as measured (treadmill distance walked in 30 minutes or until unable to continue)

        - measured in Slatis 2011 as patient response to distance in meters the patient could walk on even ground without a break
- **Certainty: Moderate**
    - **Risk of bias:** No blinding.
    - **Precision:** No serious concerns
    - **Directness:** No serious concerns
    - **Consistency:** Disability scores consistently favor surgery at 6, 12, 24 and 72 months but magnitude of effect may be marginal. Pain outcomes consistently favor surgery at 6, 12 and 24 months but no significant differences at 72 months. Walking ability (subjectively reported and objectively measured) consistently find no significant differences between groups.
    - **Other considerations:** Minor baseline differences in some patient demographics, including gender distribution. About 10% crossover rate. About 15% attrition rate.
- **Results at duration of follow-up:** 6 to 24 months [Malmivaara 2007]
    - Crossover and follow-up rates
        - Of the 50 patients who were randomized into the surgical group, 4 patients did not have surgery and 1 patient withdrew immediately after the randomization, while 4 of the 44 patients randomized into the nonoperative group were operated on during the 2-year follow-up.
        - Of the patients in the surgical and nonoperative groups, 86% and 84%, respectively, participated in all the follow-up examinations.
    - Oswestry Disability Index (ODI) (0-100 scale)
        - Mean difference favoring surgery
            - 6 months: 7.6 (95% CI 1.3-13.9)
            - 12 months: 11.3 (95% CI 4.3-18.4)
            - 24 months 7.8 (95% 0.8-14.9)
        - Improvement of 10 points or more (minimally clinically important difference)
            - 6 months: 35% nonsurgical, 59% surgical
            - 12 months: 30% nonsurgical, 63% surgical
            - 24 months: 42% nonsurgical, 55% surgical
            - Significance of between-group difference not reported; reported in discussion section and not as a primary outcome
    - Pain outcomes (0-10 scale)
        - Leg pain during walking - Mean difference favoring surgery
            - 6 months: 2.02 (95% CI 0.69-3.36)
            - 12 months: 1.69 (95% CI 0.41-2.96)
            - 24 months 1.51 (95% 0.25-2.77)
        - Low back pain during walking - Mean difference favoring surgery
            - 6 months: 2.64 (95% CI 1.40-3.88)
            - 12 months: 2.33 (95% CI 1.12-3.55)
            - 24 months 2.13 (95% 0.98-3.28)
    - Patients who underwent fusion in addition to decompression had more favorable outcomes throughout follow-up for ODI, back pain, and leg pain than those who had decompression alone
    - Self-reported walking ability – **no significant differences between groups**
    - Walking ability during treadmill test
        - Walking distance < 1,250 meters

        - Baseline: nonsurgical 46%, surgical 54%
        - 6 months: nonsurgical 39%, surgical 36%
        - 12 months: nonsurgical 38%, surgical 36%
        - 24 months: nonsurgical 35%, surgical 37%
        - No significant differences between groups
    - Walking distance < 500 meters
        - Baseline: nonsurgical 30%, surgical 32%
        - 6 months: nonsurgical 24%, surgical 22%
        - 12 months: nonsurgical 22%, surgical 20%
        - 24 months: nonsurgical 22%, surgical 26%
        - No significant differences between groups
- **Results at duration of follow-up:** 6 years [Slätis 2011]
    - 6-year follow-up analysis included 46 patients in surgical group, 39 in nonsurgical group
    - Oswestry Disability Index (ODI) (0-100 scale)
        - mean difference favoring surgery 5.6
        - consistent in direction and magnitude with differences at 6-24 months
    - Leg pain during walking score (0-10 point scale) - Mean scores find no differential effect at 6 years
        - Baseline: 6.3 nonsurgical, 6.6 surgical
        - 6 months: 4.5 nonsurgical, 2.7 surgical
        - 12 months: 4.5 nonsurgical, 2.8 surgical
        - 24 months: 4.5 nonsurgical, 2.9 surgical
        - 72 months: 4.1 nonsurgical, 4.2 surgical
    - Low back pain during walking score (0-10 point scale) - Mean scores find no differential effect at 6 years
        - Baseline: 6.8 nonsurgical, 6.9 surgical
        - 6 months: 5.4 nonsurgical, 2.9 surgical
        - 12 months: 5.1 nonsurgical, 2.8 surgical
        - 24 months: 4.8 nonsurgical, 2.7 surgical
        - 72 months: 4.4 nonsurgical, 4.1 surgical
    - Self-reported walking ability (distance in meters)
        - Increased by 100% or more in both groups at 6, 12, 24 and 72 months
        - mean and median values suggested similar improvements in both groups

MANCHIKANTI 2012a

Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Results of 2-year follow-up of a randomized, double-blind, controlled trial of fluoroscopic caudal epidural injections in central spinal stenosis. Pain Physician. 2012 Sep-Oct;15(5):371-84. PubMed [2 years of follow-up]

Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: one-year results of randomized, double-blind, active-controlled trial. J Spinal Disord Tech. 2012 Jun;25(4):226-34. PubMed [1 year of follow-up] Relevant to FAQ2b

- **Study design:** randomized controlled trial
- **Population:** 100 patients with lumbar spinal stenosis

- **Intervention:** caudal epidural injections with 1 mL of steroid (6 mg non-particulate betamethasone) mixed with local anesthetic (0.5% lidocaine 9 mL)
- **Comparison(s):** caudal epidural injections with local anesthetic (0.5% lidocaine 9 mL) alone
- **Outcomes:** primary outcome was defined as ≥ 50% improvement from baseline in numerical rating scale (NRS) for pain and/or Oswestry disability index (ODI) for function; additional outcomes included NRS, ODI, employment status, and opioid intake
- **Duration of follow-up:** 24 months
- **Certainty: Low**
    - **Risk of bias:** high loss to follow-up at 2 years (28% in intervention group and 30% in comparison group)
        - **Precision:** low precision because small- to moderate-sized trial with similar effects in both groups
        - **Directness**: not clear whether primary outcome refers to improvement in pain *or* function, or improvement in pain *and* function because of inconsistent reporting in Methods and Results in both 1-year and 2-year follow-up reports
        - primary outcome defined in Methods sections of both reports as "50% or more reduction in the NRS or ODI scores"
        - primary outcome reported in Results sections of both reports as "significant reduction in Numeric Rating Score and Oswestry disability (≥50% reduction from baseline)"
    - **Consistency:** inconsistency of data reported for the same outcomes in 2 different citations
    - **Results from 2-year-follow-up citation:**
    - comparing intervention vs. comparison groups
        - proportion of patients with ≥ 50% reduction in the NRS and/or ODI scores
            - 48% vs. 58% at 3 months
            - 50% vs. 54% at 6 months
            - 46% vs. 44% at 12 months
            - 48% vs. 40% at 18 months
            - 44% vs. 38% at 24 months
        - continuous outcome results for pain and function were similar at all time points
- **Results from 1-year follow-up citation:**
    - comparing intervention vs. comparison groups
        - proportion of patients with ≥ 50% reduction in the NRS and/or ODI scores
            - 49% vs. 58% at 3 months
            - 50% vs. 54% at 6 months
            - 46% vs. 48% at 12 months
        - continuous outcome results for pain and function were similar at all time points

MANCHIKANTI 2012b

Manchikanti L, Malla Y, Wargo BW, Cash KA, Pampati V, Fellows B. A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. *Pain Physician*. 2012 Mar-Apr;15(2):131-140. PubMed

Relevant to FAQ4

- **Study design:** prospective cohort study

- **Population:** 10,000 fluoroscopically directed epidural injections, not specific to spinal stenosis
- **Intervention:** data reported for 1,450 lumbar intralaminar epidurals and 1,310 lumbar transforaminal epidurals
- **Outcomes:** intravascular entry of the needle, profuse bleeding, local bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, infectious complications, numbness, postoperative soreness, and increased pain
- **Duration of follow-up:** patients were contacted 48 hours after injection and followed until any complications were resolved
- **Certainty: Low**
  - **Risk of bias:** Report mentions that not all patients could be contacted, but does not specify how many.
  - **Precision:** Unclear.
  - **Directness:** Types of medicine/anesthetic injected were not reported. Underlying diagnosis not reported.
  - **Consistency:** No serious concerns.
- **Results:**
  - complications in 2,760 lumbar epidural injections
  - profuse bleeding in 0.47%
    - lumbar interlaminar 0.8%
    - lumbar transforaminal 0.2%
  - intravascular penetration 4%
    - lumbar interlaminar 0.5%
    - lumbar transforaminal 7.9%
  - transient nerve root irritation 2.3%
    - lumbar interlaminar 0.28%
    - lumbar transforaminal 4.6%
  - no events of epidural hematoma, nerve damage, infection, or abscess

MANCHIKANTI 2015a

Manchikanti L, Kaye AD, Manchikanti K, Boswell M, Pampati V, Hirsch J. Efficacy of epidural injections in the treatment of lumbar central spinal stenosis: a systematic review. Anesth Pain Med. 2015 Feb 1;5(1):e23139. PubMed

Relevant to FAQ2b

- **Study design:** systematic review without meta-analysis
- **Population:** patients with lumbar spinal stenosis
- **Intervention:** 3 different anatomical epidural injection approaches (caudal, interlaminar, and transforaminal)
- **Comparison(s):** placebo or active control
- **Outcomes:** pain (primary) and function (secondary)
- **Duration of follow-up:** up to 2 years

Certainty/Results not summarized: This review lacked pooled analysis, and it was used only to find "high-quality" trials not previously identified, namely Manchikanti 2012a and Manchikanti 2015b reported to be high-quality in the review by Manchikanti.

MANCHIKANTI 2015b

Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJ. A randomized, double-blind controlled trial of lumbar interlaminar epidural injections in central spinal stenosis: 2-year follow-up. Pain Physician. 2015 Jan-Feb;18(1):79-92. PubMed

Relevant to FAQ2b

- **Study design:** randomized controlled trial
- **Population:** 120 patients with lumbar spinal stenosis
- **Intervention:** lumbar interlaminar epidural injections with 1 mL of steroid (6 mg betamethasone) mixed with local anesthetic (0.5% lidocaine 5 mL)
- **Comparison(s):** lumbar interlaminar epidural injections with local anesthetic (0.5% lidocaine 6 mL) alone
- **Outcomes:** primary outcome was defined as ≥ 50% improvement from baseline in numerical rating scale (NRS) for pain and Oswestry disability index (ODI) for function; additional outcomes included NRS, ODI, employment status, and opioid intake
- **Duration of follow-up:** 24 months
- **Certainty: Low**
    - **Risk of bias:** not clear whether the study coordinators who randomized patients were blinded to the allocation
    - **Precision:** low precision because small- to moderate-sized trial with similar effects in both groups
    - **Directness**: no serious concerns
    - **Consistency:** no serious concerns
- **Results**:
    - comparing intervention vs. comparison groups
        - proportion of patients with ≥ 50% reduction in the NRS and ODI scores
            - at 3 months 77% vs. 75%
            - at 6 months 77% vs. 72%
            - at 12 months 73% vs. 73%
            - at 18 months 75% vs. 75%
            - at 24 months 73% vs. 72%
        - continuous outcome results for pain and function were similar at all time points

MCGREGOR 2013

McGregor AH, Probyn K, Cro S, et al. Rehabilitation following surgery for lumbar spinal stenosis. Cochrane Database Syst Rev. 2013 Dec 9;(12):CD009644. PubMed

Relevant to FAQ1 (used for reminder to involve physical therapy after surgery)

- **Study design:** systematic review and meta-analysis
- **Population:** 373 adults (mean age 62-67, 41%-59% female, mean BMI 27-29.5 kg/m^2) from 3 trials who had primary spinal decompressive surgery, with or without fusion, for lumbar spinal stenosis
- **Intervention:** active rehabilitation: group or therapist-led exercise training or stabilization training involving muscle-strengthening exercises and flexibility training, and educational materials encouraging activity at 6-12 weeks after surgery for 30-90 minutes per session, once or twice weekly
- **Comparison:** usual care: limited advice provided postoperatively to stay active or brief general program of exercises

- **Outcomes:** functional status, leg pain, low back pain
- **Duration of follow-up:** 12 months

- **Certainty: Moderate**
  - **Risk of bias:** Compliance with training was not adequately described in 2 trials. Usual care was not standardized. Timing of rehab varied among trials, from 6 weeks to 3 months after surgery.
  - **Precision:** No serious concerns
  - **Directness:** Findings may not be generalizable to rehab protocols other than those studied.
  - **Consistency:** Serious inconsistency with 2 trials favoring intervention and 1 trial favoring control for functional status, leg pain, and low back pain
  - **Other considerations:**
    - **Results:**
      - in analyses of all trials, active rehabilitation associated with
        - clinically significant improvement in back-specific functional score (as measured by Oswestry Disability Index or Roland Morris Disability Questionnaire Score) up to 12 months
        - improved low back pain up to 12 months
        - reduced leg pain at 12 months, but not significant at ≤ 6 months
      - no significant difference in general health up to 12 months in 2 studies with 273 patients
      - evidence on return to work was poorly and inconsistently reported and therefore was not considered in this analysis

MO 2018

Mo Z, Zhang R, Chang M, Tang S. Exercise therapy versus surgery for lumbar spinal stenosis: a systematic review and meta-analysis. Pak J Med Sci. 2018 Jul-Aug;34(4):879-885. PubMed

Relevant to FAQ2c

- **Study design:** systematic review
- **Population:** 3 trials of 897 patients (patient characteristics not reported)
- **Intervention:** exercise therapy
  - 2 trials also included nonsteroidal anti-inflammatory drugs and education in the nonsurgical arm
- **Comparison:** decompressive laminectomy
- **Outcomes:** Oswestry Disability Index (ODI) and physical function component of SF-36 questionnaire
- **Duration of follow-up:** 2-4 years
- **Certainty: Low**
  - **Risk of bias:** One trial lacked details on randomization and allocation concealment. One trial had small sample size. Some trials did not provide details of exercise protocols.
  - **Precision:** No serious concerns.
  - **Directness:** Lack of reporting of patient characteristics limits determination of generalizability.
  - **Consistency:** High degree of heterogeneity for some outcomes and time points.
  - **Other considerations:** For the mixed-design SPORT study, only the RCT data were included in the meta-analysis (not the observational cohort data).
- **Results:**

- Meta-analysis was possible for:
  - ODI at 6 months, 1 year, and 2 years (3 trials)
  - Physical function at 6 months, 1 year, and 2 years (2 trials)
- ODI: pooled mean difference relative to baseline
  - 2.18 (95% CI -2.8 to 7.17) at 6 months
  - 4.26 (95% CI -1.79 to 10.32) at 1 year
  - 3.85 (95% CI 0.48 to 7.22) at 2 years
  - Difference significant (in favor of surgery) at 2 years only
- Physical function: pooled mean difference relative to baseline
  - -2.23 (95% CI -7.46 to 2.99) at 6 months
  - -2.17 (95% CI -7.44 to 3.1) at 1 year
  - -0.67 (95% CI -6.16 to 4.82) at 2 years
  - Differences not significant

NICE 2016

National Institute for Health and Care Excellence. Low back pain and sciatica in over 16s: assessment and management. NICE Guideline NG59. November 2016. NICE 2016 Nov:NG59
Relevant to FAQ1

- General reference used for generic information on treatment options
- Nonpharmacological interventions to consider
  - Personalized advice and information to facilitate self-management
  - Group exercise program
  - Manual therapy as part of a treatment protocol including exercise
  - Cognitive behavioral therapy
  - Combinations of the above
- Pharmacological interventions to consider
  - Oral nonsteroidal anti-inflammatory drugs (NSAIDs)
    - At lowest effective dose for shortest period of time
    - Augment with gastroprotective agents if needed
  - Weak opioids
    - With or without paracetamol
    - Consider only if NSAIDs are contraindicated, not tolerated, or ineffective

PLASTARAS 2015

Plastaras C, McCormick ZL, Garvan C, Macron D, Joshi A, Chimes G, Smeal W, Rittenberg J, Kennedy DJ. Adverse events associated with fluoroscopically guided lumbosacral transforaminal epidural steroid injections. Spine J. 2015 Oct 1;15(10):2157-65. PubMed
Relevant to FAQ3, FAQ4

- **Study design:** retrospective cohort study
- **Population:** patients with lumbosacral radicular pain who had fluoroscopically guided transforaminal epidural steroid injection
- **Intervention:** fluoroscopically guided transforaminal epidural steroid injection (2,025 injections in 1,295 consecutive patients)
- **Comparison(s):** not applicable
- **Outcomes:** adverse events immediately and 24-72 hours after procedure

- **Duration of follow-up:** 74 hours after procedure
- **Certainty**: Low
- **Results**:
    - immediate adverse events
        - overall in 9.2% of injections
        - most common
            - vasovagal reaction in 4.2%
            - interrupted procedure from intravascular flow in 1.7%
    - delayed adverse events
        - overall in 20% of injections
        - most common
            - pain exacerbation in 5.0%
            - injection site soreness in 3.9%
            - headache in 3.9%
            - facial flushing/sweating in 1.8%
            - insomnia in 1.6%

SALMENKIVI 2017

Salmenkivi J, Sund R, Paavola M, Ruuth I, Malmivaara A. Mortality caused by surgery for degenerative lumbar spine. Spine. 2017 Jul 15;42(14):1080-1087. PubMed

Relevant to FAQ4

- **Study design:** registry-based cohort study
- **Population:** 61,166 adults (mean age 52 years, 48% female) who had their first operation due to a degenerative lumbar spine disorder between 1997 and 2009
    - 20,584 patients (34%) with spinal stenosis (mean age 66 years, 58% female)
    - 36,511 patients (60%) with herniated disk (mean age 44 years, 41% female)
    - 1,270 patients (2%) with degenerative disk disease (mean age 52 years, 60% female)
    - 2,801 patients (5%) with spondylolysis or spondylolisthesis (mean age 49 years, 56% female)
- **Intervention:** spinal surgery (discectomy, decompression, and/or fusion)
- **Comparison:** none
- **Outcomes:** mortality rate (deaths related to surgery), causes of death
- **Duration of follow-up:** 1 year
- **Certainty: Moderate**
    - **Risk of bias:** Registry study with limited data on baseline characteristics, medication use, other adjunctive treatments, and outcomes.
    - **Precision:** No serious concerns
    - **Directness:** Registry data dates back to 1997, so findings may not be entirely generalizable to current techniques and protocols. Findings may not be generalizable to countries other than Finland.
    - **Consistency:** No serious concerns
- **Results:**
    - Rates of mortality attributable to spinal surgery or postoperative care
        - Overall 0.08%
        - **Spinal stenosis 0.19%**
        - Herniated disk 0.02%
        - Degenerative disk disease 0%

        - Spondylolysis or spondylolisthesis 0.07%
    - Mortality categorization
        - Medical error in 2 cases
            - Both were spinal stenosis patients
        - Fatal sequelae after surgery in 28 cases
            - 25 were spinal stenosis patients
        - Pre-existing underlying disease exacerbated by surgery in 19 cases
            - 13 were spinal stenosis patients
    - Most common causes of death
        - Myocardial infarction (16 patients)
        - Cerebral infarction or bleeding (7 patients)
        - Pneumonia (7 patients)
        - Pulmonary embolism (5 patients)

STAATS 2016

Staats PS, Benyamin RM; MiDAS ENCORE Investigators. MiDAS ENCORE: Randomized controlled clinical trial report of 6-month results. Pain Physician. 2016 Feb;19(2):25-38. PubMed [6 months of follow-up]

Benyamin RM, Staats PS, MiDAS Encore I. MILD is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. Pain Physician. 2016 May;19(4):229-242 PubMed [1 year of follow-up]
Relevant to FAQ2c

- **Study design:** randomized trial
- **Population:** 302 Medicare beneficiaries with lumbar spinal stenosis, ligamentum flavum hypertrophy, and neurogenic claudication refractory to conservative management
    - Surgical group: 149 patients (mean age 76 years, 50% female)
    - Injection group: 153 patients (mean age 75 years, 62% female)
- **Intervention:** MILD percutaneous lumbar decompression, followed by adjunctive conservative therapy (other than injection) as needed
- **Comparison**: fluoroscopically guided interlaminar epidural steroid injection, followed by adjunctive conservative therapy as needed
    - 80 mg of triamcinolone (Kenalog) or methylprednisolone (Depo-Medrol) during initial injection
        - 40 mg for patients with diabetes (prevalence of diabetes not reported)
    - Between 40 and 80 mg during subsequent injections
    - 2 months or longer between injections
    - Mean 1.7 injections per patient (median 1) in the first 6 months
- **Outcomes:**
    - Primary efficacy endpoint: Oswestry Disability Index (ODI)
        - 0-100 point scale
        - response defined as 10-point improvement
    - Numeric Pain Rating Scale (NPRS)
        - 0-10 point scale
        - response defined as 2-point improvement

    - Zurich Claudication Questionnaire (ZCQ)
        - Symptom severity (pain and neuroischemic subdomains): 1-5 point scale
        - Physical function: 1-4 point scale
            - Response defined as 0.5-point improvement for the above domains
        - Patient satisfaction with treatment: 1-4 scale
            - Score of 2.5 points or lower = satisfied
- **Certainty: Low**
    - **Risk of bias:** No patient blinding, allocation concealment unclear. Some differences between groups at baseline, with both sex (about 50% men in surgical group and 38% men in epidural steroid injection group) and facet arthropathy (about 77% in surgical group and 86% in epidural steroid group) being statistically-significantly different. Many patients had spinal issues other than claudication and ligamentum flavum hypertrophy (e.g., scoliosis, herniated disk) that were not accounted for in analysis. Methods section notes that patients with diabetes received a different injection dose, but numbers of patients with diabetes and outcomes specific to those patients were not reported. Adverse event rates based on enrollment sample sizes; other outcomes based on as-treated sample sizes. Higher attrition in the control group.
    - **Precision:** No serious concerns.
    - **Directness:** Lack of no-treatment or sham control. Responder rates may not be generalizable to a real-world setting with greater patient access to adjunctive pain therapy (use of adjunctive conservative therapies was restricted). (In addition, this study does not represent the interventions and comparators (noninvasive control such as physical therapy) in the intended evidence review.)
    - **Consistency:** No serious concerns.
- **Results at duration of follow-up:** 6 months [Staats 2016]
    - 143 patients in surgical group and 131 in injection group received treatment
    - 143 patients in surgical group and 129 in injection group analyzed at 6 months
    - Use of medication for neurogenic claudication
        - Rates based on data available for 133 surgical patients and 109 injection patients
        - Surgical group: 91% at baseline, 90% at 6 months
        - Injection group: 83% at baseline, 85% at 6 months
        - No significant differences between groups or between time points
    - Response rate at 6 months, surgical group vs. injection group
        - ODI: 62% vs. 36% ($p < 0.001$)
        - NPRS: 56% vs. 33% ($p < 0.001$)
        - ZCQ
            - Pain symptoms: 58% vs. 47% ($p = 0.011$)
            - Neuroischemic symptoms: 50% vs. 30% ($p = 0.001$)
            - Physical function: 52% vs. 14% ($p < 0.001$)
            - Patient satisfaction ≤ 2.5: 65% vs. 30% ($p < 0.001$)
        - All rates calculated based on 143 surgical patients/129 injection patients
    - Device- or procedure-related adverse events
        - 1.3% of patients in each group had non-serious adverse events ($p = 1$)
        - Rates were calculated based on number of patients randomized (149 surgical/153 injection)
        - Most common adverse events for surgery
            - Mild procedural hemorrhage 0.7%

            - Procedural pain 0.7%
        - Most common adverse events for injection
            - Sinus bradycardia 0.7%
            - Back pain 0.7%
            - Extremity pain 0.7%
            - Note: the same patient had both back pain and extremity pain
- **Results at duration of follow-up:** 1 year [Benyamin 2016]
    - MILD procedure took significantly longer (mean 43 minutes vs 7.7 minutes) than epidural steroid injection and required different types of anesthesia (mostly MAC [monitored anesthesia care] sedation)
    - Responders: MILD procedure vs. epidural steroid injection at 1 year
        - improved back and leg pain in 57.3% vs. 27.1% ($p < 0.001$, NNT 4)
        - improved functional disability in 58% vs. 27.1% ($p < 0.001$, NNT 4)
        - improved symptom severity in 51.7% vs. 31.8% ($p = 0.001$, NNT 5)
        - improved physical function in 44.1% vs. 17.8% ($p < 0.001$, NNT 4)
        - improved patient satisfaction in 61.5% vs. 33.3% ($p < 0.001$, NNT 4)
        - device- or procedure-related adverse events in 2 patients vs. 3 patients (not significant)
        - no significant differences in the use of medications for neurogenic claudication

TRUSZCYNSKA 2013

Truszcynska A, Rapala K, Truszczynski O, Tarnowski A, Lukawski S. Return to work after spinal stenosis surgery and the patient's quality of life. Int J Occup Med Environ Health. 2013 Jun;26(3):394-400. PubMed

Relevant to FAQ5

- **Study design:** retrospective cohort study
- **Population:** 58 patients (mean age 52 years, 50% female) treated surgically for lumbar spinal stenosis in Poland
    - 39 patients (67%) had professions involving heavy lifting
    - 19 patients had professions involving sitting for a long time
- **Intervention:** surgical treatment of lumbar spinal stenosis (types of procedures not specified)
- **Comparison:** none
- **Outcome:** return to work rate
- **Duration of follow-up:** 3 to 8 months
- **Certainty: Low**
    - **Risk of bias:** Cohort study design. No control group. Type of surgery and other protocol details were not specified or analyzed separately. Preoperative symptoms and disability were not reported.
    - **Precision:** Confidence intervals were not reported, but rather small sample suggests precision would not be good
    - **Directness:** Findings may not be generalizable to older patients, patients in countries other than Poland, or surgical techniques other than those studied
    - **Consistency:** No serious concerns.
- **Results:**

    - 38% were retired, collecting disability pensions, or unemployed before surgery
    - 24.1% (14/58) patients returned to work after surgery
        - 22.4% between 6 weeks and 6 months
        - 1.7% at < 6 weeks
    - 75.9% (44/58) did not return to work after surgery
        - 16 patients considered themselves unfit to work
        - 22 patients did not feel like working again

TYE 2017a

Tye EY, Anderson JT, Haas AR, et al. Decompression versus decompression and fusion for degenerative lumbar stenosis in a workers' compensation setting. Spine. 2017 Jul 1;42(13):1017-1023. PubMed
Relevant to FAQ5

- **Study design:** retrospective cohort study
- **Population:** 364 patients with degenerative spinal stenosis (without instability or deformity) receiving workers' compensation and treated with lumbar decompression with or without fusion
- **Intervention:** decompression plus fusion (137 patients: mean age 49 years, 66% male, 39% heavy-labor occupation)
- **Comparison:** decompression alone (227 patients: mean age 50 years, 70% male, 31% heavy-labor occupation)
- **Outcome:** return to work after surgery (defined as return within 2 years and continue working for > 6 months)
- **Duration of follow-up:** 3 years
- **Certainty: Low**
    - **Risk of bias:** Cohort study design. No nonoperative control group. Severity of preoperative condition was not quantified. Third-party data may have been incomplete. Requirement that patients maintain work status for 6 months after return may overlook patients who did improve with surgery but not to that extent.
    - **Precision:** Confidence intervals were reported only for predictive variables.
    - **Directness:** Findings may not be generalizable to women, older patients, non-workers' comp patients, workers' comp patients in states other than Ohio, or surgical protocols other than those studied.
    - **Consistency:** No serious concerns.
- **Results:**
    - mean time to surgery 1,214 days (3.3 years) for decompression alone vs 1,695 days (4.6 years) for decompression and fusion ($p < 0.01$)
    - return to work in 36% of 227 patients treated with decompression alone compared to 24% of 137 patients treated with decompression and fusion ($p = 0.01$)
    - Reoperation rates were similar between groups (14% vs. 17%, $p = 0.4$)
        - Only 18 patients in the decompression-only cohort (8%) required an arthrodesis later

TYE 2017b

Tye EY, Anderson JT, Haas AR, et al. The timing of surgery affects return to work rates in patients with degenerative lumbar stenosis in a workers' compensation setting. Clin Spine Surg. 2017 Dec;30(10):E1444-E1449. PubMed
Relevant to FAQ5

- **Study design:** retrospective cohort study
- **Population:** 227 adults with degenerative lumbar spinal stenosis receiving workers' compensation.
- **Intervention:** lumbar decompression (without fusion) within 1 year of symptom onset
    - 50 patients (mean age 50 years, 76% male, 32% heavy-labor occupation)
    - Mean time to surgery: 210 days
- **Comparison:** lumbar decompression (without fusion) more than 1 year from symptom onset
    - 177 patients (mean age 50 years, 68% male, 30% heavy-labor occupation)
    - Mean time to surgery: 1,499 days
- **Outcome:** return to work after surgery (defined as return within 2 years and continue working for > 6 months)
- **Duration of follow-up:** 3 years
- **Certainty: Low**
    - **Risk of bias:** Cohort study design. No nonoperative control group. Date of symptom onset based on patient recall. Severity of preoperative condition was not quantified. Third-party data may have been incomplete. Requirement that patients maintain work status for 6 months after return may overlook patients who did improve with surgery but not to that extent.
    - **Precision:** Confidence intervals were reported only for predictive variables.
    - **Directness:** Findings may not be generalizable to women, older patients, non-workers' comp patients, workers' comp patients in states other than Ohio, or surgical protocols other than those studied.
    - **Consistency:** No serious concerns.
- **Results:**
    - return to work in 50% of 50 patients treated with decompression within 1 year of symptom onset, compared to 30% of 177 patients treated with decompression more than 1 year after symptom onset ($p = 0.01$)
    - rates of postoperative infection, reoperation, and failed back syndrome did not differ significantly between groups

ULLRICH 2009

Ullrich PF. Lumbar laminectomy surgery for spinal stenosis (open decompression). Available at: https://www.spine-health.com/treatment/back-surgery/lumbar-laminectomy-surgery-spinal-stenosis-open-decompression Updated Oct 21, 2009. Accessed Sep 24, 2018.
Relevant to FAQ1

- General reference used for lumbar laminectomy (open decompression) procedure
    - Performed in a hospital
    - Surgeon makes a 2-to-5-inch incision in the midline of the back, and the left and right erector spinae are dissected off the lamina
    - Lamina is removed to allow visualization of nerve roots
    - Facet joints may be trimmed to give nerve roots more room
    - Patients stay in hospital for 1-3 days
    - Patients encouraged to walk immediately following surgery
    - Typically recommended to avoid excessive physical activity for 6 weeks postsurgery

VASIGH 2016

Vasigh A, Jaafarpour M, Khajavikhan J, Khani A. The effect of gabapentin plus celecoxib on pain and associated complications after laminectomy. J Clin Diagn Res. 2016 Mar;10(3):UC04-UC08. PubMed
Relevant to FAQ3

- **Study design:** randomized trial
- **Population:** 114 adults (mean age 49-50 years, 18%-34% female) undergoing elective laminectomy under general anesthesia
- **Intervention:** 200 mg celecoxib plus 300 mg gabapentin 2 hours before surgery and 6 hours after surgery
- **Comparisons:**
    - 600 mg gabapentin 2 hours before surgery and 300 mg 6 hours after surgery
    - placebo capsule orally 2 hours before surgery and 6 hours after surgery
- **Outcomes:** pain, anxiety, patient satisfaction, morphine consumption, side effects
- **Duration of follow-up:** 24 hours
- **Certainty: Moderate**
    - **Risk of bias:** Guidelines for morphine use as rescue medication and time point for assessment of morphine use were not specified. Conditions or symptoms leading to laminectomy were not described or quantified. Patient selection, inclusion and exclusion criteria were not provided.
    - **Precision:** Confidence intervals were not reported.
    - **Directness:** Findings may not be generalizable to older patients or protocols and doses other than those studied.
    - **Consistency:** Gabapentin findings are consistent with previous studies.
    - **Other considerations:** Single center study.
- **Results:**
    - Pain severity (0- to 10-point visual analog scale)
        - 2 hours post-op: placebo 7.6, gabapentin 4.9, gabapentin plus celecoxib 4; $p < 0.001$
        - 12 hours post-op: placebo 2.9, gabapentin 1.6, gabapentin plus celecoxib 1.5; $p < 0.001$
        - 24 hours post-op: placebo 1.4, gabapentin 0.7, gabapentin plus celecoxib 0.6; $p < 0.001$
    - Morphine consumption
        - Placebo 30 mg
        - Gabapentin 11.9 mg
        - Gabapentin plus celecoxib 8.1 mg
    - Patient satisfaction at 24 hours
        - Good rating: placebo 11%, gabapentin 50%, gabapentin plus celecoxib 58%; $p < 0.05$
        - Excellent rating: placebo 0%, gabapentin 24%, gabapentin plus celecoxib 29%; $p < 0.05$
    - Side effects
        - Pruritus: placebo 45%, gabapentin 18%, gabapentin plus celecoxib 21%; $p < 0.05$
        - Nausea: placebo 45%, gabapentin 13%, gabapentin plus celecoxib 29%; $p < 0.05$

- Drowsiness: placebo 5%, gabapentin 42%, gabapentin plus celecoxib 34%; p < 0.001
- Shivering: placebo 42%, gabapentin 11%, gabapentin plus celecoxib 16%; p < 0.05
- Vomiting: placebo 40%, gabapentin 10%, gabapentin plus celecoxib 16%; p < 0.05
- Dizziness: placebo 21%, gabapentin 34%, gabapentin plus celecoxib 34%; p = 0.37
- Urine retention: placebo 24%, gabapentin 13%, gabapentin plus celecoxib 16%; p = 0.43
- Headache: placebo 11%, gabapentin 13%, gabapentin plus celecoxib 16%; p = 0.79

WEINSTEIN 2007

Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. N Engl J Med. 2007 May 31;356(22):2257-70. PubMed [2 years of follow-up]

Abdu WA, Sacks OA, Tosteson ANA, et al. Long-term results of surgery compared with nonoperative treatment for lumbar degenerative spondylolisthesis in the Spine Outcomes Research Trial. Spine. 2018 Dec 1;43(23):1619-1630. PubMed [8-years of follow-up]
Relevant to FAQ2c

- **Study design:** randomized, controlled trial that was part of the Spine Patient Outcomes Research Trial [SPORT] study group, which enrolled patients with spinal stenosis and radiculopathy in 1 of 4 studies:
  - randomized trial comparing surgery vs. nonoperative treatment in patients with degenerative spondylolisthesis who consented to randomization (described here)
  - randomized trial comparing surgery vs. nonoperative treatment in patients without degenerative spondylolisthesis who consented to randomization (described below under Weinstein 2008)
  - prospective observational study in patients with degenerative spondylolisthesis who consented to follow-up but selected treatment course without randomization
  - prospective observational study in patients without degenerative spondylolisthesis who consented to follow-up but selected treatment course without randomization
- **Population:** 304 randomized. Inclusion criteria for SPORT study were:
  - age > 18 years
  - neurogenic claudication or radicular leg symptoms
  - spinal stenosis demonstrated on cross-sectional imaging (and degenerative spondylolisthesis on standing lateral x-rays for the 2 spondylolisthesis studies; again, this study concerns those with degenerative spondylolisthesis))
  - persistent symptoms for at least 12 weeks
  - determination that patients were surgical candidates
- **Intervention:** Surgery was standard posterior decompressive laminectomy with or without bilateral single-level fusion (iliac crest bone grafting with or without posterior pedicle screw instrumentation)

- **Comparison:** Nonoperative treatment included active physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatory drugs if tolerated
- **Outcomes:** primary end points were the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) bodily pain and physical function scores and the Oswestry Disability Index
- **Certainty: Low**
    - **Risk of bias:** High rate of crossover affects intention-to-treat (ITT) analysis; non-ITT analyses are functionally observational analyses. High loss to follow-up at 8 years. No blinding.
    - **Precision:** No serious concerns
    - **Directness**: No serious concerns
    - **Consistency**: Inconsistency between ITT analyses and as-treated analyses.
- **Results at duration of follow-up:** 2 years [Weinstein 2007]
    - No significant difference in primary outcomes in intention-to-treat analysis of randomized trial
    - With such high crossover rates, authors combined randomized and nonrandomized cohorts and analyzed as observational study according to treatment actually received - 372 patients had surgery, 235 patients had nonsurgical treatment
        - 304 patients randomized to surgery vs. conservative treatment
            - of 159 patients randomized to surgery, only 57% had surgery at 1 year and 64% at 2 years
            - of 145 patients randomized to nonsurgical treatment, 44% had surgery at 1 year and 49% at 2 years
        - 303 patients included in observational cohort
            - 173 patients chose surgery, of whom 97% had surgery at 1 year and 97% at 2 years
            - 130 chose nonsurgical treatment, of whom 17% had surgery at 1 year and 25% at 2 years
        - Comparing surgery vs. nonsurgical treatment at 2 years in combined observational as-treated analysis
            - mean change in bodily pain score 29.9 vs. 11.7 ($p < 0.05$) on a 0 to 100 scale with higher score indicating less severe symptoms
            - mean change in physical function score 26.6 vs. 8.3 ($p < 0.05$) on a 0 to 100 scale with higher score indicating less severe symptoms
            - mean change in disability index -24.2 vs. -7.5 ($p < 0.05$) on a 0 to 100 scale with lower score indicating less severe symptoms
            - 68.8% vs. 32.2% very or somewhat satisfied with symptoms
            - 74.1% vs. 24.1% self-rated major improvement
    - **Results at duration of follow-up:** 8-years [Abdu 2018]
        - Surgery rates/crossover
            - Of 159 patients randomized to surgery, 64% had surgery at 2 years and 72% at 8 years
            - Of 145 patients randomized to conservative care, 49% had surgery at 2 years and 54% at 8 years
            - Of 173 patients choosing surgery, 97% had surgery at 2 years and 98% by 8 years
            - Of 130 patients choosing conservative care, 25% had surgery by 2 years and 38% by 8 years

        - 8-year follow-up analysis included 211 of 304 randomized patients and 174 of 303 observational cohort patients.
    - mean change in bodily pain score from baseline comparing surgery vs. conservative care (on a 0 to 100 scale with higher change in score indicating greater reduction in severity of symptoms)
        - in intention-to-treat analysis (as randomized)
            - at 5 years, 24.2 vs. 24.5 (treatment effect -0.2, 95% CI -6.8 to 6.3)
            - at 8 years, 20 vs. 20.9 (treatment effect -0.9, 95% CI -7.7 to 5.9)
        - in as-treated analysis (combined analysis of randomized and observational cohorts)
            - at 5 years, 27.1 vs. 16.1 (treatment effect 10.9, 95% CI 6.7 to 15.2)
            - at 8 years, 26.4 vs. 14.6 (treatment effect 11.8, 95% CI 7.2 to 16.4)
    - mean change in disability index with surgery vs. conservative care from baseline (on a 0 to 100 scale with lower change in score indicating less improvement in function)
        - in intent to treat analysis (randomized)
            - at 5 years, -13.8 vs. -17.9 (treatment effect 4.1, 95% CI -0.8 to 9)
            - at 8 years, -11.2 vs. -16.2 (treatment effect 5, 95% CI 0 to 10.1)
        - in as-treated analysis (combined analysis of randomized and observational cohorts)
            - at 5 years, -19.1 vs. -10.4 (treatment effect -8.7, 95% CI -11.9 to -5.3)
            - at 8 years, -18.1 vs. -7.9 (treatment effect -10.3, 95% CI -13.6 to -6.9)
    - Self-reported satisfaction at 8 years
        - Very or somewhat satisfied with symptoms
            - ITT: 51.8% for surgery vs. 58.2% for nonsurgical (treatment effect -6.4, 95% CI -21.3 to 8.4)
            - As treated: 64.1% for surgery vs. 30.8% for nonsurgical (treatment effect 33.3, 95% CI 22.2 to 44.4)
        - Very or somewhat satisfied with care
            - ITT: 80% for surgery vs. 80.4% for nonsurgical (treatment effect -0.4, 95% CI -13.5 to 12.8)
            - As treated: 83.9% for surgery vs. 61.6% for nonsurgical (treatment effect 22.2, 95% CI 10 to 34.5)
        - Major improvement from baseline
            - ITT: 31.4% for surgery vs. 30.2% for nonsurgical (treatment effect 1.2, 95% CI -12.6 to 15)
            - As treated: 40.5% for surgery vs. 10.5% for nonsurgical (treatment effect 20, 95% CI 9.7 to 30.3)

WEINSTEIN 2008

Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med. 2008 Feb 21;358(8):794-810. PubMed [2 years of follow-up]

Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the Spine Patient Outcomes Research Trial. Spine. 2010 Jun 15;35(14):1329-1338. PubMed [4 years of follow-up]
Relevant to FAQ2c

- **Study design:** randomized, controlled trial that was part of the Spine Patient Outcomes Research Trial [SPORT] study group, which enrolled patients with spinal stenosis and radiculopathy in 1 of 4 studies:
    - randomized trial comparing surgery vs. nonoperative treatment in patients with degenerative spondylolisthesis who consented to randomization (described above in Weinstein 2007)
    - randomized trial comparing surgery vs. nonoperative treatment in patients without degenerative spondylolisthesis who consented to randomization (described here)
    - prospective observational study in patients with degenerative spondylolisthesis who consented to follow-up but selected treatment course without randomization
    - prospective observational study in patients without degenerative spondylolisthesis who consented to follow-up but selected treatment course without randomization
- **Population:** 289 randomized. Inclusion criteria for SPORT study were:
    - age > 18 years
    - neurogenic claudication or radicular leg symptoms
    - spinal stenosis demonstrated on cross-sectional imaging
    - persistent symptoms for at least 12 weeks
    - determination that patients were surgical candidates
- **Intervention:** Surgery was standard posterior decompressive laminectomy with or without bilateral single-level fusion (iliac crest bone grafting with or without posterior pedicle screw instrumentation)
- **Comparison:** Nonoperative treatment included active physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatory drugs if tolerated
- **Outcomes:** primary end points were the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) bodily pain and physical function scores and the Oswestry Disability Index
- **Certainty: Low**
    - **Risk of bias:** High rate of crossover makes intention-to-treat (ITT) analysis uninterpretable; non-ITT analyses are functionally observational analyses. No blinding.
    - **Precision:** No serious concerns
    - **Directness**: No serious concerns
    - **Consistency**: Inconsistency between ITT analyses and as-treated analyses.
- **Results at duration of follow-up:** 2 years [Weinstein 2008]
    - in intention-to-treat analyses of randomized trial
        - no significant differences in any of 3 primary outcomes (bodily pain, physical function, Oswestry Disability Index) at 1 year
        - no significant differences in 2 of 3 primary outcomes (physical function, Oswestry Disability Index) at 2 years
        - small but statistically significant difference favoring surgery in bodily pain at 2 years
    - with such high crossover rates, authors combined randomized and nonrandomized cohorts and analyzed as observational study according to treatment actually received
        - 289 patients randomized to surgery vs. conservative treatment
            - of 138 patients randomized to surgery, only 63% had surgery at 1 year and 67% at 2 years and 68% at 4 years
            - of 151 patients randomized to nonsurgical treatment, 42% had surgery at 1 year and 43% at 2 years and 49% at 4 years
        - 365 patients included in observational cohort

        - 219 patients chose surgery, of whom 95% had surgery at 1 year and 96% at 2 years and 97% at 4 years
        - 146 chose nonsurgical treatment, of whom 17% had surgery at 1 year and 22% at 2 years and 26% at 4 years
    - comparing surgery vs. nonsurgical treatment at 2 years in combined observational as-treated analysis
        - mean change in bodily pain score 26.9 vs. 13.3 ($p < 0.05$) on a 0 to 100 scale with higher score indicating less severe symptoms
        - mean change in physical function score 23 vs. 11.8 ($p < 0.05$) on a 0 to 100 scale with higher score indicating less severe symptoms
        - mean change in disability index -20.5 vs. -9.3 ($p < 0.05$) on a 0 to 100 scale with lower score indicating less severe symptoms
        - 68.2% vs. 29.6% very or somewhat satisfied with symptoms
        - 62.9% vs. 28.7% self-rated major improvement
- **Results at duration of follow-up:** 4 years [Weinstein 2010]
    - mean change in bodily pain score from baseline comparing surgery vs. conservative care (on a 0 to 100 scale with higher change in score indicating greater reduction in severity of symptoms)
        - in intention-to-treat analysis (as randomized)
            - at 2 years, 23.2 vs. 15.4 ($p < 0.05$)
            - at 3 years, 21 vs. 16.6 (not significant)
            - at 4 years, 15.9 vs. 15.7 (not significant)
        - in as-treated analysis (combined analysis of randomized and observational cohorts)
            - at 2 years, 27 vs. 12.9 ($p < 0.05$)
            - at 3 years, 26.8 vs. 13.4 ($p < 0.05$)
            - at 4 years, 25.1 vs. 12.5 ($p < 0.05$)
    - mean change in disability index with surgery vs. conservative care from baseline (on a 0 to 100 scale with lower change in score indicating less improvement in function)
        - in intent to treat analysis (randomized)
            - at 2 years, -16.1 vs. -12.7 (not significant)
            - at 3 years, -14.7 vs. -13.3 (not significant)
            - at 4 years, -12.2 vs. -12.4 (not significant)
        - in as-treated analysis (combined analysis of randomized and observational cohorts)
            - at 2 years, -20.3 vs. -9.4 ($p < 0.05$)
            - at 3 years, -18.6 vs. -9.1 ($p < 0.05$)
            - at 4 years, -18.7 vs. -9.3 ($p < 0.05$)

ZAINA 2016

Zaina F, Tomkins-Lane C, Carragee E, Negrini S. Surgical versus non-surgical treatment for lumbar spinal stenosis. Cochrane Database Syst Rev. 2016 Jan 29;(1):CD010264. PubMed
Relevant to FAQ2c, FAQ4

- **Study design:** systematic review and meta-analysis

- **Population:** 643 adults (mean age > 59 years in all trials) with congenital or degenerative narrowing, or both, of the spinal canal with displacement or compression or deformity of neural elements
- **Intervention:**
    - nerve decompression by partial or total laminectomy, medial facetectomy or discectomy
    - minimally invasive mild decompression
    - segmental decompression with facetectomy
    - posterior decompressive laminectomy
    - interspinous implant
- **Comparison(s):**
    - Bracing and rehabilitation
    - Epidural steroid injection
    - Nonsteroidal anti-inflammatory drugs (NSAIDS) and physical therapy
    - Physical therapy, exercise, and NSAIDs
    - Epidural steroid injection plus NSAIDs, other pain relievers, and/or physical therapy
- **Outcomes:** pain and disability
- **Duration of follow-up:** 6 weeks to 10 years
- **Certainty: Low**
    - **Risk of bias:** Only 1 trial (N = 38) had an overall low risk of bias.
    - **Precision:** No serious concerns
    - **Directness:** No serious concerns
    - **Consistency:** Differences in treatment modalities employed make assessment of consistency difficult. High heterogeneity where assessable.
        - Amundsen 2000 is essentially a trial of surgery plus conservative/noninvasive therapy versus conservative/noninvasive therapy alone.
        - Brown 2012 assesses the MILD® procedure (a minimally invasive decompression surgery) versus epidural steroid shots.
        - Zucherman assesses the X STOP procedure (an interspinous implant) versus conservative/noninvasive therapy and epidural corticosteroid injections.
        - Malmivaara 2007 and Weinstein 2008 test standard decompressive surgery versus conservative therapy. Between Malmivaara 2007 and Weinstein 2008, degree of heterogeneity was prominent at 6-month and 1-year timepoints (I^2 = 72% and 81%, respectively), but not at 2-year timepoint (I^2 = 17%).
    - **Other considerations:** Conservative treatments were not standardized or consistent between trials, and typically were poorly described. Specific outcome tools varied among trials.
- **Results:**
    - purpose of surgery for spinal stenosis (descriptive summary for consideration for FAQ1)
        - Surgery is done to increase the amount of space in the spinal canal through removal of portions of spinal elements such as lamina and is generally referred to as decompression.
        - Removal of spine structures may exacerbate existing instability or create de novo instability following decompression. Spinal fusion is sometimes added to the decompression procedure to avoid or treat this instability.
    - no difference in pain with decompressive surgery with or without fusion vs. usual conservative care (bracing or exercise) in 1 trial with 31 patients
        - Risk ratio (RR) 1.38 (95% CI 0.22-8.59) at 3 months

        - RR 7.5 (95% CI 1-56.48) at 4 years
        - RR 4.09 (95% CI 0.95-17.58) at 10 years
        - See the evidence summary earlier in this report for Amundsen 2000. The results reported in Zaina 2016: (1) Use numerators for the conservative therapy group that are based on only those who were randomized to and stayed in the conservative therapy group, and (2) do not adjust the denominator for the death that occurred in the conservative therapy group (but they do adjust the denominators for the deaths that occurred in the surgery group).
    - Oswestry Disability Index comparing decompressive surgery with or without fusion to usual conservative care
        - All analyses based on pooling 2 trials (Malmivaara 2007, Weinstein 2008)
        - At 6 months: Mean difference -3.66 (95% CI -10.12 to +2.80) (n = 349)
        - At 1 year: Mean difference -6.17 (95% CI -15.02 to +2.67) (n = 340)
        - At 2 years: Mean difference -4.43 (95% CI -7.91 to -0.06) (n = 315)
    - No minor adverse events in 2 studies with 69 patients
    - Serious adverse events
        - 10% intraoperative complications (mainly dural tear or spinal fluid leak) and 10% postoperative complications (including wound hematoma, infection, and other unspecified problems) and 13% reoperation rate within 4 years reported in 138 patients receiving surgery in 1 trial (Weinstein 2008)
        - intraoperative or postoperative complications (lesions on dural sac, neural dysfunction) in 24% of 50 patients receiving surgery in 1 trial (Malmivaara 2007)
        - spinous process fracture, coronary ischemia, respiratory distress, hematoma, pulmonary edema in 11% of 100 patients receiving interspinous device surgery in 1 trial (Zucherman 2004)

Part 4 - Evidence Review Tables

Methods

For each FAQ the key concepts (results and factors affecting certainty of the results) from the critically appraised evidence reports that are most relevant to evidence synthesis will be summarized in Evidence Review Tables. Where evidence is very limited, or the FAQ is for descriptive summary, summary text will be provided.

Results

FAQ 1: What does the treatment involve?

Conservative/noninvasive therapy

Descriptive Evidence Details

The DynaMed Plus Overview & Recommendations for lumbar spinal stenosis includes physical therapy or exercise, lumbosacral corsets, and medications (analgesics, gabapentin) as noninvasive options. These recommendations are based in part on evidence-based guidelines from the North American Spine Society (NASS) and the National Institute for Health and Care Excellence (NICE).

DynaMed Plus presents initial recommendations for treatment of lumbar spinal stenosis as:

Consider nonsurgical treatment for patients with mild or moderate symptoms of lumbar spinal stenosis (Weak recommendation). Options include:

- limited course of active physical therapy (Weak recommendation)
- lumbosacral corset for improvement in walking distance and decreased pain while the corset is worn (Weak recommendation)
- medications have insufficient evidence to recommend for or against use, but may include:
  - acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), although there is no evidence of benefit in patients with lumbar spinal stenosis
  - mild narcotic analgesics in patients who are unresponsive to or intolerant of NSAIDs
  - gabapentin

The NASS guideline (Kreiner 2013) includes:

- insufficient evidence to recommend for or against physical therapy or exercise as stand-alone treatment for degenerative lumbar spinal stenosis (NASS Grade I)
- limited course of active physical therapy is an option for treatment

- insufficient evidence to recommend for or against pharmacological treatment in management of spinal stenosis (NASS Grade I)

The NICE guideline includes:

- Nonpharmacological interventions to consider
  - Personalized advice and information to facilitate self-management
  - Group exercise program
  - Manual therapy as part of a treatment protocol including exercise
  - Cognitive behavioral therapy
  - Combinations of the above
- Pharmacological interventions to consider
  - Oral nonsteroidal anti-inflammatory drugs (NSAIDs)
    - At lowest effective dose for shortest period of time
    - Augment with gastroprotective agents if needed
  - Weak opioids
    - With or without paracetamol
    - Consider only if NSAIDs are contraindicated, not tolerated, or ineffective

Epidural injections

Descriptive Evidence Details

EBSCO Health Library information on Spinal Corticosteroid Injection includes:

- Corticosteroids, typically along with an anesthetic, are injected into the epidural space around the spinal nerve roots of the lumbar portion of the spine to relieve pain or inflammation.
- The procedure can be performed in a hospital or outpatient facility and takes about 30-60 minutes. Recovery will be monitored after the injection.
- Anesthesia is not required, but may be used if needed.
- Temporary pain at the site of injection may occur and is usually treated by applying an ice pack.

Surgery

Descriptive Evidence Details

Ullrich 2009 provides a description of the decompressive surgery procedure:

- Lumbar laminectomy (open decompression) procedure
  - Performed in a hospital
  - Surgeon makes a 2-to-5-inch incision in the midline of the back, and the left and right erector spinae are dissected off the lamina
  - Lamina is removed to allow visualization of nerve roots
  - Facet joints may be trimmed to give nerve roots more room
- Patients stay in hospital for 1-3 days
- Patients encouraged to walk immediately following surgery
- Typically recommended to avoid excessive physical activity for 6 weeks postsurgery

A Cochrane review (McGregor 2013) found 3 randomized trials of active rehabilitation after spinal decompressive surgery for lumbar spinal stenosis. Active rehabilitation was associated with clinically significant improvement in back-specific functional score up to 12 months, improved low back pain up to 12 months, and reduced leg pain at 12 months (but not significant before 6 months). (Moderate certainty) This Cochrane review is included to support the recommendation to consider active rehabilitation an expectation with the surgery option.

FAQ 2: Will it help my pain or function?

FAQ 2a: What is the likelihood of meaningful pain/function improvement with conservative/noninvasive treatment?

Evidence Review Table for FAQ2a – Systematic Reviews

Citation	Study type	Sample size	Treatment	Follow-up time	Key findings	Quality of evidence	Notes
Ammendolia 2013	Systematic review of randomized trials	200 (4 trials)	Physical therapy / exercise regimens Goren 2010 (n = 45) had a no-treatment control. Pua 2007 (n = 68), Whitman 2006 (n = 58) and Koc 2009 (n = 29) compared different physical therapy and/or exercise regimens.	Mostly 2-6 weeks	Goren 2010 found exercise may be better than no treatment for short-term leg pain and function. Koc 2009 found addition of inpatient physical therapy to a home exercise program and oral diclofenac may improve short-term pain intensity, function, and quality of life. Pua 2007 found no clear short-term difference in two exercise regimens. Whitman 2006 found a difference in short-term global improvement comparing two physical therapy/exercise regimens	Very low	Small samples sizes, heterogeneity, methodologic concerns (risk of bias assessment leading to assessments of very low to low quality of evidence), possible indirectness (unclear if populations studied are similar in severity to surgery cohorts)
		286 (3 trials)	Oral medication Matsudaira 2009 (n = 79) studied a	8 weeks to 6 months (Waikakul 2000 followed for	Improvements in some continuous measures of pain and function compared to the control group	Very low	Small sample sizes, clinical heterogeneity in treatments and control groups,

			prostaglandin E1 derivative versus etodolac, Waikakul 2000 (n = 152) studied different doses of vitamin B12, Yaski 2007 (n = 55) studied gabapentin versus placebo	up to 2 years, but the randomized intervention only occurred for 6 months)			methodologic concerns (as noted above), possible indirectness (as noted above)
Kreiner 2013	Systematic review of case series	350 (4 studies)	Nonoperative treatment included physical therapy and exercise, massage, epidural steroid injections, oral medications, and multimodal nonoperative care	2 years (2 studies) 3 years (1 study) 10 years (1 study)	50% to 70% have improvement in pain 40% have improvement in function (1 study, n = 91) Ability to walk 1,000 meters without claudication increased from 18% to 85% (1 study, n = 82)	Very low	Small sample sizes, heterogeneity, possible indirectness (unclear if populations studied are similar in severity to surgery cohorts)

The calcitonin trials in Ammendolia 2013 not summarized here because all trials failed to show benefit beyond placebo (5 trials) or acetaminophen (1 trial); all trials were considered to provide very low quality evidence.

Mo 2018 is not summarized here – the included trials (Delitto 2015, Malmivaara 2007, and Weinstein 2008) are summarized.

Zaina 2016 is not summarized here -- the most relevant trial data are already summarized. Brown 2012 and Zucherman 2004 had a noninvasive control group that included epidural injection. Amundsen 2000 (n = 31) had a conservative therapy control group who were "fitted with an orthosis and transferred to the rehabilitation department for 1 month" and received no regular physiotherapy except for "instruction and 'back school'" (though Amundsen 2000's findings suggested this control therapy might be at least as good as, and possibly even better than, receiving surgery).

Evidence Review Table for FAQ2a – Cohort analyses

Citation	Study type	Sample size	Treatment	Follow-up time	Key findings	Quality of evidence	Notes
Delitto 2015	Randomized trial (control arm)	73 (of 82 randomized) in intention-to-treat analysis 29 in as-treated analysis	Physical therapy, exercises, patient education	2 years	55% improved (i.e., improvement in physical function of > 0.5 SD relative to baseline) 52% improved in as-treated analysis	Moderate	Small sample size, 11% attrition rate
Malmivaara 2007, Slatis 2011	Randomized trial (control arm)	44	Oral NSAIDs plus 1-3 physical therapy treatments	6, 12 and 24 months	35%/30%/42% rate of improvement (by 10 points [minimally important difference] in Oswestry disability index) at 6/12/24 months	Moderate	Small sample size, Response rate not reported at 6 years

Weinstein 2008, Weinstein 2010	Randomized trial plus cohort analysis (control arm – as treated analysis combining randomized and observational cohorts)	Varied from 198 to 370*	Physical therapy, exercises, patient education	2 years, 3 years, 4 years	Mean change in pain 12.5-13.4 and function 9.1-9.4 points on 0-100 scales depending on time point assessed	Low	High loss to follow-up, High crossover rate
	Randomized trial (control arm – intention to treat analysis)	151 randomized, data available from 113 to 135	Physical therapy, exercises, patient education	2 years, 3 years, 4 years	Mean change in pain 15.4-16.6 and function 12.4-13.3 points on 0-100 scales depending on time point assessed	Low	High loss to follow-up, high crossover rate

*From Weinstein 2008: "The number of patients in the as-treated analyses reflects the number of patients contributing to the estimate in a given period with the use of the longitudinal-modeling strategy (explained in the Methods section) and may not correspond to the number shown for each visit time in Figure 1."

FAQ 2b: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with epidural steroid injection?

Evidence Review Table for FAQ2b – Systematic Reviews

Citation	Sample size	Follow-up time	Key findings*	Quality of evidence	Notes
Ammendolia 2013				No new information	See Critical Appraisal report
Chou 2015	821 (8 trials)	6 weeks to 21 months	**Improvements in pain and function at 1-2 weeks (1 trial, n = 29);** no significant improvements after 2 weeks (up to 5 trials, n = 615)	Low	All but 1 trial had high risk of bias, Mismatch between expected and included trials in pooled analyses (see Critical Appraisal report)
Liu 2015				Unusable	See Critical Appraisal report
Manchikanti 2015a				Unusable	See Critical Appraisal report

*Statistically significant findings noted in **bold**.

Evidence Review Table for FAQ2b – Randomized Trials

Citation	Sample size	Follow-up time	Key findings*	Quality of evidence	Notes
Friedly 2014, Friedly 2017	400	3 weeks, 6 weeks, 12 weeks, 6 months, 1 year	**Small improvements in disability and leg pain scores favor steroid at 3 weeks.** Little to no additional efficacy at 6 weeks. No differences at 12 weeks, 6 months or 1 year.	Moderate (3-6 weeks), Low (12 weeks to 1 year)	Baseline differences in pain duration. High crossover rate after 6 weeks.
Manchikanti 2012a	100	3, 6, 12, 18 and 24 months	No significant differences in any pain or function measure at any time.	Low	High loss to follow-up. Sample size too small to conclude absence of effect.
Manchikanti 2015b	120	3, 6, 12, 18 and 24 months	No significant differences in any pain or function measure at any time.	Low	Allocation concealment unclear. Sample size too small to conclude absence of effect.

*Statistically significant findings noted in **bold**.

FAQ 2c: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with surgery?

Evidence Review Table for FAQ2c – Systematic Reviews

Citation	Sample size	Surgery	Comparator	Follow-up time	Key findings*	Quality of evidence	Notes
Mo 2018	897 (3 trials)	Decompressive laminectomy	Exercise therapy (2 trials also included NSAIDs and education)	6 months, 1 year, 2 years	Pooled MD in change from baseline in ODI (0-100 scale) favoring surgery: 2.18 at 6 months, 4.26 at 1 year, **3.85 at 2 years**. Pooled MD in change from baseline in SF-36 physical function not significant at any time	Low	High degree of heterogeneity for some outcomes. Risk of bias in underlying trials.
Zaina 2016	643 (5 trials)	Varied	Varied		Only 2 trials could be pooled (noted below)	Low	Only 1 trial at low risk of bias.
	349 (2 trials)	Decompressive laminectomy	Usual care	6 months, 1 year, 2 years	Mean difference in ODI favoring surgery 3.66 at 6 months, 6.17 at 1 year**, 4.43 at 2 years**		
	31 (1 trial)	Decompressive laminectomy	Usual care	3 months, 4 years, 10 years	Relative risk for pain improved 1.38 at 3 months, 7.5 at 4 years, 4.09 at 10 years.		

*Statistically significant findings noted in **bold**. MD = mean difference, ODI = Oswestry disability index (0-100 scale).

Evidence Review Table for FAQ2c – Randomized Trials

Citation	Sample size	Surgery	Comparator	Follow-up time	Key findings*	Quality of evidence	Notes
Amundsen 2000	31	Decompressive laminectomy	Conservative treatment	3 months, 4 years, 10 years	No significant differences between groups. Relative risk for pain improved 0.4 at 3 months, 3.54 at 4 years, 1.93 at 10 years.	Low	Small sample size. Allocation concealment unclear. No blinding. High crossover rate.
Brown 2012	38	Minimally Invasive Lumbar Decompression (MILD)	Single epidural steroid injection	6 weeks	**2-point improvement in pain (0-10 scale) in 76% surgery vs. 35% control**, mean change in disability (0-100 scale) -11.4 surgery vs. -5.7 control	Low	Small sample size. 100% control group crossed over at 6 weeks. Indirect comparator.
Delitto 2015	169	Decompressive laminectomy without fusion	Physical therapy, exercise, education	10, 26, 52 and 104 weeks	Mean physical function scores improved from 25-30 to 40-50 in both groups. Successful outcome at 2 years noted in 61% vs. 53%	Low	No blinding. Wide confidence intervals
Malmivaara 2007, Slatis 2011	94	Decompressive laminectomy	NSAIDs, 1-3 physical therapy visits	6 months, 1 year, 2 years, 6 years	**Mean difference in ODI favoring surgery 7.6 at 6 months, 11.3 at 1 year, 7.8 at 2 years, 5.4 at 6 years.** **10-point improvement in ODI in 59% vs. 35%, 63% vs. 30% and 55% vs. 42% at 6/12/24 months** (not reported at 6 years)	Moderate	No blinding.

					Pain scores favor surgery at 6/12/24 months but no difference at 6 years No differences in walking distance at 6/12/24/72 months.		
Staats 2016, Benyamin 2016	302	MILD (injection therapy not allowed)	Epidural steroid injection	6 months	**10-point improvement in ODI (0-100) in 62% vs. 36%, 2-point improvement in pain (0-10) in 56% vs. 33%**	Low	No blinding. Allocation concealment unclear. Baseline differences. Indirect comparator.
Weinstein 2007, Weinstein 2018	304	Decompressive laminectomy	Physical therapy, education, exercise, NSAIDs	2 years, 8 years	No significant differences in ITT analysis; **improvements in pain, function and satisfaction in as-treated analysis**.	Low	No blinding. High crossover rate. Inconsistency between ITT analysis and as-treated analysis.
Weinstein 2008, Weinstein 2010	289	Decompressive laminectomy	Physical therapy, education, exercise, NSAIDs	2 years, 3 years, 4 years	No significant differences in ITT analysis **(except mean change in pain at 2 years only)**; **improvements in pain, function and satisfaction in as-treated analysis**.	Low	No blinding. High crossover rate. Inconsistency between ITT analysis and as-treated analysis (adding observational cohorts).

*Statistically significant findings noted in **bold**. ODI = Oswestry disability index (0-100 scale), ITT = intention-to-treat.

FAQ 3: What are the side effects?

Conservative/noninvasive therapy

Evidence Review Description for FAQ3 – Conservative therapy

Data derived from Ammendolia 2013 (and Kreiner 2013), reporting on randomized trials

In a trial of exercise with 68 patients, 1 patient reported increase in symptoms with exercise (Very low certainty)

In a trial of NSAIDs with 79 patients, about 5% reported gastrointestinal upset (Low certainty)

In a placebo-controlled trial of gabapentin with 55 patients, Drowsiness and dizziness reported with gabapentin (rates not reported) (Moderate certainty)

Epidural injections

Evidence Review Table for FAQ3 – Epidural steroid injections

Citation	Cohort Type	Sample Size	Key Findings – Incidence of side effects	Certainty
Bhat 2005	Prospective controlled	100 patients	12% dysphonia or throat symptoms (for < 1 week) with epidural steroid (vs. 0% with diagnostic injection)	High
Botwin 2000	Retrospective	165 patients	8.8% side effects per epidural injection (2.7% non-positional headache for up to 24 hours, 1.9% injection site pain for up to 24 hours, 1.2% facial flushing)	Low
Botwin 2001	Retrospective	139 patients	15.6% side effects per epidural injection (4.7% insomnia, 3.5% non-positional headache for up to 24 hours, 3.1% injection site pain for up to 24 hours, 2.3% facial flushing)	Low
El Abd 2015	Prospective	150 patients	21% side effects within first 30 minutes (13% numbness and tingling in limb, 5% perineal pruritus) 47% side effects within 1 day - most commonly injection site pain (17%), headaches (14%), insomnia (14%), increased radicular pain (9%), rash/flush (4%) 13% side effects at 1-3 days (mostly increased radicular pain)	Low
Everett 2004	Prospective	240 patients	9% flushing with methylprednisolone, 16% flushing with betamethasone	Low
Friedly 2014	Randomized trial	400 patients	29% adverse events (fever/infection in 5%, headache in 4%)	Moderate
Karaman 2011	Prospective	1305 injections	11.5% minor complications, most frequently vasovagal reaction (8.7%)	Low

		(562 patients)		
Kim 2010	Retrospective	150 patients	28% flushing, all resolved within 48 hours	Low
Kranz 2015	Retrospective	497 injections	2% interlaminar and 8% transforaminal injections had inadvertent intravascular injection during review of CT fluoroscopy images	Moderate
Plastaras 2015	Retrospective	2025 injections (1295 patients)	9.2% immediate side effects – most common vasovagal reaction (4.2%) 20% delayed side effects – most common pain exacerbation (5%), site pain (4%), headache (4%), facial flushing/sweating (1.8%), insomnia (1.6%)	Low

Surgery

Evidence Review Description for FAQ3 – Surgery

Side effects were not well reported in evidence regarding surgery, despite four rounds of searching as defined by the systematic methodology. In one randomized trial with 169 patients (Delitto 2015), 33 surgery-related complications were reported. The details were not clearly reported but the complications included "other surgery" and "wound healing/site infection". (Very low certainty)

To evaluate surgery-related pain (a commonly expected side effect), additional searches for cohort studies and randomized controlled trials of postoperative analgesic therapy were conducted to find pain courses described in intervention or control groups.

Choi 2013 randomized 120 patients having lumbar spinal surgery to addition of dexamethasone or placebo injection to a course of oral pregabalin. Outcomes for patients with herniated disk and spinal stenosis were not reported separately. Median pain scores (on 0-100 scale, at rest and with movement) were 20-30 at 12 hours after surgery, 30-50 at 24 hours after surgery, 10-30 at 48 hours and 72 hours after surgery, and 0 at 1-6 months after surgery. (Low certainty)

Vasigh 2016 randomized 114 patients having laminectomy to celecoxib plus gabapentin, gabapentin, or placebo before and after surgery. Mean pain severity (0-10 scale) in the placebo group was 7.6 at 2 hours postoperatively, 2.9 at 12 hours and 1.4 at 24 hours. Side effect rates were as high as 45% for pruritus with placebo, 45% for nausea with placebo, 42% for drowsiness with gabapentin, 42% for shivering with placebo, and 40% for vomiting with placebo. (Moderate certainty)

Gebershagen 2013 was a cohort study of 50,523 adults reporting pain intensity after surgery, including 1,702 having spinal decompression, fusion or laminectomy. Underlying diagnoses were not reported. Mean "worst pain" scores within 24 hours after surgery were in the 4-7 range on a 0-10 scale. Severe pain (6 or higher) was reported in 35% patients having spinal canal decompression and 72% having spinal fusion. Extreme pain (8 or higher) was reported in 15% patients having spinal canal decompression and 45% having spinal fusion. (Low certainty)

FAQ 4: What are the risks?

Conservative/noninvasive therapy

Evidence Review Description for FAQ4 – Conservative therapy

Data derived from Ammendolia 2013 (and Kreiner 2013), reporting on randomized trials, only mentioned 1 serious adverse event:

In a trial of physical therapy with 29 patients, 1 patient developed angina pectoris (Very low certainty)

Epidural injections

Evidence Review Description for FAQ4 – Epidural injections

No major complications reported in numerous studies reporting side effects (see FAQ 3). Friedly 2014 reported 5 of 200 patients (2.5%) in the epidural steroid injection group having serious adverse events requiring hospitalization and/or surgery but did not consider any of these events to be procedure-related. In a cohort of 2,760 lumbar epidural injections (not specifying diagnosis or therapies injected), Manchikanti 2012b reported 0.47% rate of profuse bleeding. (Low certainty)

Surgery

Evidence Review Description for FAQ4 – Surgery

Serious adverse effects were not well reported in evidence regarding surgery. The most relevant findings are described here.

In one randomized trial with 169 patients (Delitto 2015), a 25% rate of "surgery-related complications" were reported. The details were not clearly reported but the complications included "other surgery" and "wound healing/site infection". In this trial there were 4 deaths reported in surgery patients and 2 deaths in control patients, but it was reported to not be considered treatment-related. (Very low certainty)

In one systematic review of randomized trials (Zaina 2016), 2 trials with 50 and 138 patients having surgery reported serious adverse events in 24% and 20% patients. Examples of serious adverse events reported include dural tear, infection, neural dysfunction, and hematoma. (Low certainty)

In a registry-based cohort study in Finland with 20,584 patients having surgery for spinal stenosis (Salmenkivi 2017), deaths related to surgery reported in 0.19%. (Moderate certainty)

In one retrospective cohort study of 284 patients (Lee 2017), 27% had postoperative urinary retention more than 2 days after surgery. This is consistent with 24% rate of postoperative urine retention reported in the placebo group in a randomized trial of postoperative analgesics (Vasigh 2016) (Moderate certainty).

In one systematic review of surgical cohorts with specific attention to the complication of reoperation for instability, Guha 2015 evaluated 2,496 patients from 24 cohorts. They reported 1.8% required

reoperation for instability. Heterogeneity was not assessed for this pooled analysis. (Moderate certainty)

Longer-term reoperation rates after surgery (not clearly attributable to adverse events or lack of efficacy) noted in the review of evidence for other specified FAQs were 14% to 17% at 3 years in a cohort of 364 patients (Tye 2017a), 13% at 4 years in 138 patients receiving surgery in 1 trial (Weinstein 2008), and 23% at 8-10 years in a cohort of 97 patients (Atlas 2005, PMID 15834339).

FAQ 5: How long does it take to recover?

Evidence Review Description for FAQ5 – Surgery

Harris 2012 evaluated 476 patients treated with decompressive surgery (with or without fusion) and who were receiving workers compensation in Australia. 50% returned to work 24 months after surgery. (Low certainty)

Herno 1996 evaluated 439 patients who had lumbar spinal stenosis surgery in Finland. About 40% returned to work. None of the patients who had retired before surgery returned to work. Predictors of return to work were age < 50 years and being fit to work at the time of surgery. (Low certainty)

Truszczynska 2013 evaluated 58 patients (mean age 52 years) who had lumbar spinal stenosis surgery in Poland. 24% returned to work, mostly between 6 weeks and 6 months after surgery. Return to work rates could be lower because 38% were retired, collecting disability pensions, or unemployed before surgery. (Low certainty)

Tye 2017a evaluated 364 patients treated with decompressive surgery and receiving workers compensation for degenerative lumbar stenosis. Return to work (defined as return within 2 years and continued working for > 6 months) was achieved by 36% of 227 patients treated with decompression alone and 24% patients treated with decompression plus fusion. (Low certainty)

Tye 2017b evaluated the 227 patients treated with decompression alone. Return to work was achieved in 50% of 50 patients who had surgery within 1 year of symptom onset and 30% of 177 patients who had surgery more than 1 year after symptom onset. (Low certainty)

Alhammoud 2017 provided a systematic review of 6 studies (304 patients) evaluating driving safety after spinal surgery. Driving reaction time varied across studies and results ranged from “safe to drive immediately” to recommending no driving until 3 months after surgery. Driving reaction time varied with level of spinal fusion, with possibly longer time to safety following multilevel spinal fusion. Some lumbar surgery studies suggest that driving reaction time may be prolonged by pain, while others found no correlation between pain and reaction time. (Very low certainty)

Part 5 - Evidence Synthesis

Methods

Evidence synthesis process

Synthesis methods will be based on the most appropriate methods matching the available evidence. We will systematically consider synthesis methods with the following questions:

Are the evidence results appropriate to support combined synthesis for a single result as the best representation of the body of evidence?

State "Yes" or "No", and provide explanation if "No".

If the results are appropriate for quantitative synthesis, what method is best fit?

Pick one of the following and justify:

(1) meta-analysis already done

(2) meta-analysis created from the evidence results

(3) median of sufficiently-valid results, stating cutoff for validity

(4) median of all results

If not appropriate for quantitative synthesis, what method is best to represent the evidence synthesis?

Pick one of the following and justify:

(1) range of all results

(2) range of sufficiently valid results

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

(4) statement of inconsistency too limiting for single synthesized conclusion

Where evidence is very limited, or the FAQ is for descriptive summary, such that summary text was provided instead of Evidence Review Tables, the Descriptive Evidence Summary will be noted.

Results

FAQ 1: What does the treatment involve?

Conservative/noninvasive therapy

Descriptive Evidence Summary

Options for treating lumbar spinal stenosis (without epidural injections or surgery) include physical therapy, exercise, lumbosacral corsets (a support brace), and medications (mostly pain relievers)

Epidural injections

Descriptive Evidence Summary

Corticosteroids, typically along with an anesthetic, are injected into the epidural space around the spinal nerve roots of the lumbar portion of the spine to relieve pain or inflammation. The procedure can be performed in a hospital or outpatient facility and takes about 30-60 minutes.

Surgery

Descriptive Evidence Summary

Surgery is done to increase the amount of space in the stenotic spinal canal. Hospital stay after surgery ranges from 1 to 3 days. Physical therapy 6 to 12 weeks after surgery may improve patients' pain and ability to carry out everyday tasks at 12 months, based on a Cochrane review of 3 trials.

FAQ 2: Will it help my pain or function?

FAQ 2a: What is the likelihood of meaningful pain/function improvement with conservative/noninvasive treatment?

Evidence Synthesis Process for FAQ2a

Are the evidence results appropriate to support combined synthesis for a single result as the best representation of the body of evidence?

No, the evidence results from 3 systematic reviews of randomized trials (Ammendolia 2013, Mo 2018, Zaina 2016) and 1 systematic review of case series (Kreiner 2013) are very low certainty due to small sample sizes, heterogeneity, and indirectness (unclear if the populations studies are similar in severity to surgery cohorts). In the absence of usable results from systematic reviews 3 included cohorts from randomized trials (Delitto 2015, Malmivaara 2007/Slatis 2011, Weinstein 2008/Weinstein 2010) were not amenable to quantitative synthesis due to inconsistencies in interventions and outcomes..

If not appropriate for quantitative synthesis, what method is best to represent the evidence synthesis?

Pick one of the following and justify:

(1) range of all results

(2) range of sufficiently valid results

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

(4) statement of inconsistency too limiting for single synthesized conclusion

Two cohort analyses (control arms from randomized trials) provided Moderate certainty evidence (Delitto 2015, Malmivaara 2007/Slatis 2011). Both these studies reported response rates (a dichotomous measure of the likelihood of meaningful pain/function improvement) at 6 months, 12 months, and/or 2 years. **The likelihood of meaningful improvement ranged from 30% to 55%.**

Symptom improvement was reported as early as two weeks in some trials.

FAQ 2b: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with epidural steroid injection?

Evidence Synthesis Process for FAQ2b

Are the evidence results appropriate to support combined synthesis for a single result as the best representation of the body of evidence?

No, the evidence results are highly limited in certainty. Four systematic reviews (Ammendolia 2013, Chou 2015, Liu 2015, Manchikanti 2015a) were unusable as critical appraisal found numerous errors in trial quality assessment and inclusion/exclusion decisions for specific pooled analyses. Systematic reviews were used to obtain the three "high-quality" trials (Friedly 2014/Friedly 2017, Manchikanti 2012a, Manchikanti 2015b) and evaluation of those trials found them to be mostly low certainty as well.

If not appropriate for quantitative synthesis, what method is best to represent the evidence synthesis?

Pick one of the following and justify:

(1) range of all results

(2) range of sufficiently valid results

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

(4) statement of inconsistency too limiting for single synthesized conclusion

The evidence is too limited to suggest quantified results at specific timepoints, but there is moderate certainty evidence (1 trial with 400 patients, 1 trial with 29 patients) of small improvements in pain and disability at 1-3 weeks attributable to epidural steroid injections. (*Friedly 2014, noted in Chou 2015)*

There is low certainty evidence (3-5 trials with > 600 patients) that there is little to no steroid-attributable efficacy at 6 weeks through 2 years. (*Friedly 2014/Friedly 2017, Manchikanti 2012a, Manchikanti 2015b, meta-analysis in Chou 2015*)

FAQ 2c: What is the change in likelihood of meaningful pain/function improvement (treatment-related efficacy) with surgery?

Evidence Synthesis Process for FAQ2c

Are the evidence results appropriate to support combined synthesis for a single result as the best representation of the body of evidence?

No, the pooled results from two systematic reviews (Mo 2018, Zaina 2016) were low certainty due to risk of bias in the underlying trials and high heterogeneity for some outcomes. Evaluation of 7 randomized trials found inconsistencies in types of surgeries and controls (Brown 2012 and Staats 2016/Benyamin 2016 compared a minimally invasive percutaneous surgery to epidural steroid injection), and inconsistencies in types of analyses (Weinstein 2007/2018 and Weinstein 2008/2010 reported intention-to-treat analyses which were inconsistent with as-treated analyses).

If not appropriate for quantitative synthesis, what method is best to represent the evidence synthesis?

Pick one of the following and justify:

(1) range of all results

(2) range of sufficiently valid results

(3) descriptive summary without quantitative representation (e.g., consistency in direction, but inconsistency in magnitude)

(4) statement of inconsistency too limiting for single synthesized conclusion

A range of all results would not be meaningful because there are:

- multiple results finding no substantial treatment-related efficacy (Amundsen 2000, Brown 2012, Delitto 2015, Malmivaara 2007/Slatis 2011, Weinstein 2007/2018, Weinstein 2008/2010),
- multiple results suggesting small degrees of treatment-related efficacy (Malmivaara 2007/Slatis 2011, Weinstein 2007/2018, Weinstein 2008/2010), and
- some results suggesting moderate or larger degrees of treatment-related efficacy (Brown 2012, Staats 2016/Benyamin 2016).

All but one trial is low certainty so there is no “range of sufficiently valid results”. The one trial with moderate certainty (Malmivaara 2007/Slatis 2011) did not have blinding and had results consistent with treatment-related efficacy and results consistent with no treatment-related efficacy. Specifically;

- Disability (using the Oswestry disability index with 0-100 scale) was improved by 7.6 points more with surgery at 6 months, by 11.3 more points at 1 year, by 7.8 points more at 2 years, and by 5.4 points more at 6 years.
- Pain scores favored surgery at 6 months, 1 year and 2 years but not at 6 years.

- Walking ability (self-reported and measured walking distances) showed no differences between groups at 6 months, 1 year, 2 years and 6 years. Walking ability improved with both groups similarly compared to baseline.

Two trials compared minimally invasive lumbar decompression (MILD, a percutaneous procedure) to epidural steroid injection therapy (Brown 2012, Staats 2016/Benyamin 2016). Both suggested substantial efficacy for surgery, but these trials did not directly address our prespecified research question.

A descriptive summary of the evidence supports conclusions that many patients will experience meaningful improvement in pain and/or function after surgery (and also after conservative therapy), but it is not possible to determine if the surgery is directly and causally related to the improvements experienced.

Improvements were noted as early as 6 weeks, 3 months or 6 months.

FAQ 3: What are the side effects?

Conservative/noninvasive therapy

Descriptive Evidence Summary

Side effects with conservative/noninvasive therapy depend on the specific therapy. Side effects are rarely reported with exercise therapy. Side effects are more commonly reported with medications, such as about 5% people having gastrointestinal upset when using NSAIDs.

Epidural injections

Evidence Synthesis Process for FAQ3 – Epidural injections

Are the evidence results appropriate to support combined synthesis for a single result as the best representation of the body of evidence?

No, the evidence results are inconsistent in outcomes reported and incidence rates.

If not appropriate for quantitative synthesis, what method is best to represent the evidence synthesis?

(1) range of all results

The rate of side effects with epidural steroid injections have been reported to be as low as 9% and as high as 47%.

Numbness and tingling in the limb, occurring within the first 30 minutes, is reported in up to 13%.

Side effects resolving within 24 hours have also included injection site pain (up to 17%), headache (up to 14%), and insomnia (up to 14%).

Flushing has been reported in up to 28% injections, all resolving within 48 hours.

Increased radicular pain has been reported in up to 9% or more and may persist for a few days.

Dysphonia or throat symptoms have been reported in 12%, mostly resolving within 1 week.

Surgery

Descriptive Evidence Summary

Side effects with surgery are not well reported. Surgery-related pain can be severe in the first day or for a few days after lumbar spinal surgery, based on pain courses described in short-term postoperative studies. The duration of postoperative pain is not well documented. The most common postoperative side effects (reported in up to 45% patients) are those related to the pain management strategy and include nausea, vomiting, pruritus, drowsiness, shivering, dizziness, urine retention and headache.

FAQ 4: What are the risks?

Conservative/noninvasive therapy

Descriptive Evidence Summary

Complications with conservative/noninvasive therapy depend on the specific therapy.

Epidural injections

Descriptive Evidence Summary

No major complications clearly rated to the treatment have been reported among thousands of patients receiving epidural steroid injections.

Surgery

Descriptive Evidence Summary

Complications with surgery are not well reported. Rates of serious adverse events (such as dural tears, infection, hematoma, and neural dysfunction) have ranged from 11% to 25% in randomized trials. Postoperative urinary retention was reported in 24% to 27% patients in two studies. A systematic review of nearly 2,500 surgeries found 1.8% require reoperation for instability. One national registry reported 0.19% mortality with surgery.

FAQ 5: How long does it take to recover?

Conservative/noninvasive therapy

Descriptive Evidence Summary

It depends on the specific therapy, but there is generally no recovery time needed.

Epidural injections

Descriptive Evidence Summary

Side effects such as headache may interfere with some activities, but such side effects usually resolve within 24 hours.

Surgery

Descriptive Evidence Summary

24% to 50% of patients having surgery return to work after surgery, mostly between 6 weeks to 6 months after surgery. Return to work rates may be low because many patients having surgery were retired, collecting disability payments, or unemployed. *(Harris 2012, Herno 1996, Truszcynska 2013, Tye 2017a, Tye 2017b)*

Driving reaction times vary with some studies suggesting waiting up to 3 months after surgery before returning to driving. *(Alhammoud 2017)*

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